PB85-147304

# Guidance for the Reregistration of Pesticide Products Containing Butylate as the Active Ingredient

(U.S.) Environmental Protection Agency
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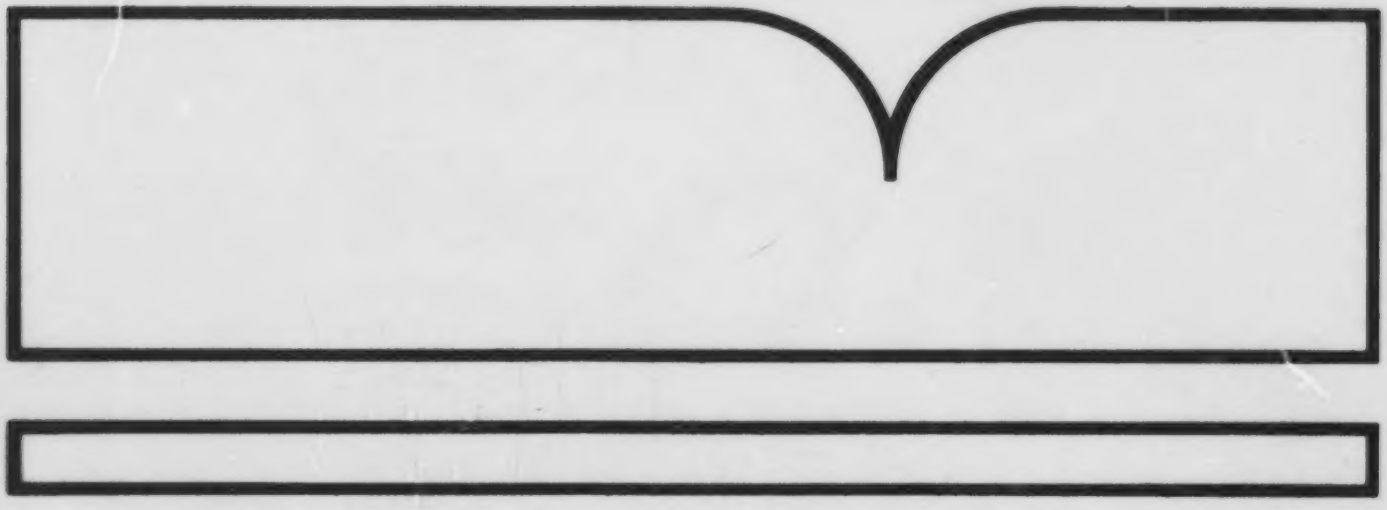

U.S. Department of Commerce
National Technical Information Service
NTIS

PB85-147304

# GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

# CONTAINING BUTYLATE

# AS THE ACTIVE INGREDIENT

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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This document contains information regarding reregistration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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## INTRODUCTION

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA Section 3(g), as amended in 1978, directs EPA to reregister all pesticides as expeditiously as possible. Each registrant of a manufacturing use product of the active ingredient who wishes to continue to sell or distribute that product must apply for reregistration.

To fulfill this Congressional mandate, we have established the Registration Standards program which will review all pesticide active ingredients first registered before January 1, 1977. These pesticides will be reviewed in use clusters which are prioritized on the basis of a ranking scheme giving preference to pesticides used on food and feed crops.

The Registration Standards program involves a thorough review of the scientific data base underlying pesticide registrations and an identification of essential but missing studies which may not have been required when the product was initially registered or studies that are now considered insufficient. Our reassessment results in the development of a regulatory position, contained in this document, on each pesticide and its uses. The regulatory position may require the registrant to modify product labels to provide additional precautionary statements, restrict the use of the pesticide to certified applicators, provide reentry intervals, modify uses or formulation types, specify certain packaging limitations, or other requirements to assure that proper use of the pesticide poses no potential adverse effects to human health or the environment.

The scientific review, which is not contained herein but is available upon request, concentrates on the technical grade of the active ingredient and identifies missing generic data. However, during the review of these data we are also looking for potential hazards that may be associated with the formulated (end-use) products that contain the active ingredient. If we find serious concerns, we will bring formulated products under the provisions of the Registration Standards program to the extent necessary to protect the public.

EPA has the authority under FIFRA §3(c)(2)(B) to require that certain registrants submit generic data that will answer our questions regarding the hazard that may result from the intended use of the pesticide under review. Further, §3(c)(2)(B) provides that these data are to be submitted by those registrants who do not qualify for the formulator's exemption [FIFRA §3(c)(2)(D)]. Normally, this means that the registrants who are responsible for filling the data gaps are the manufacturing-use product producers (basic

suppliers of the active ingredient). However, end-use producers will not qualify for the formulator's exemption if the source of their active ingredient: (1) is not registered with EPA, and/or (2) is produced by the registrant's firm, or a firm which has ownership in common with the registrant's firm. These end-use producers can qualify for the formulator's exemption if they change their source of supply to a registered source, provided the source does not share ownership in common with the registrant's firm. If the end-use product registrant decides to switch sources, a new Confidential Statement of Formula, EPA Form 8570-4, must be submitted to the appropriate Product Manager within 90 days of receipt of this Guidance Document. The chart on the following page shows what is generally required of those who do and do not qualify for the formulator's exemption in the Registration Standards program.

If you decide to request the Agency to discontinue the registration of any of your products subject to the reregistration requirements of this Guidance Document, please notify the Product Manager named in the cover letter, within 90 days from the receipt of this document, that you wish to voluntarily cancel the registration(s). If you decide to maintain your product registration(s), you must provide the information described in the following pages within the timeframes outlined. EPA will issue a notice of intent to cancel or suspend the registration of any currently registered product if you fail to comply with the requirements set forth in this Guidance Document.

This Guidance Document will be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because this situation is currently unresolved, EPA has decided to proceed with the requirements in this Guidance Document which do not relate to compliance with the §3(c)(1)(D) provisions and to supplement the Document with additional guidance when circumstances permit. Failure to comply with the provisions of the subsequent guidance will also result in issuance by EPA of an intent to cancel the affected product registration(s).

Registrants are reminded that §6(a)(2) of FIFRA requires you at any time to submit factual information raising concerns of possible unreasonable adverse effects of a pesticide. You should notify the Agency of interim results of studies in progress if those results show possible adverse effects.

| PRODUCTS SUBJECT TO THE REGISTRATION STANDARDS PROGRAM | ACTION(S) REQUIRED TO MAINTAIN REGISTRATION |
|---|---|
| I. Products That Do Not Qualify For The Formulator's Exemption | |
| A. Single Active Ingredient Products* | These products must be reregistered. To obtain reregistration, labeling, packaging and data requirements must be satisfied in accordance with the Registration Standards Guidance Document. |
| B. Multiple Active Ingredient Products | These products will not be reregistered at this time. However, generic data required to continue the registration of the active ingredient under review, as described in the Registration Standards Guidance Document, will be required and some labeling precautions may also be required. |
| II. Products That Do Qualify For The Formulator's Exemption | Only when additional restrictions or labeling are needed to protect man or the environment will these products be subject to the Registration Standard requirements. Affected products will be dealt with in a variety of ways, including but not limited to the Label Improvement Program and special intent to cancel notices. |

* End-use products of registrants who also produce a manufacturing-use product will not be required to be reregistered provided that registrant fulfills the requirements specified in the Guidance Document for manufacturing-use product(s). Such end-use products will be subject to the labeling changes required for products in "II" above. If there are no manufacturing-use products registered by any company end-use products will be required to be reregistered.

NOTE: If all registrants in "I" above fail to meet the requirements in I-A and B above, then the registrants in "II" lose their right to qualify for the formulator's exemption and become subject to the requirements in I-A and B.

# I. Regulatory Position and Rationale

## A. Introduction

This Chapter describes the regulatory position of the Environmental Protection Agency, hereafter referred to as "the Agency", on all manufacturing-use products (MPs) containing the herbicide butylate as the sole active ingredient. The Agency's position is based on an evaluation of all registered uses, and products containing butylate. This document also considers labeling requirements, tolerances, "Special Local Needs" (registrations authorized by Section 24(c) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA)), as well as Federal registrations granted or pending under Section 3 of the FIFRA. In addition, this document sets forth the data requirements that must be met to register MPs covered by this Standard.

This document addresses registration requirements for MPs (containing butylate) and their intermediaries. Butylate MPs that differ appreciably from those described here may require amendments to the Standard. End-use products will be addressed under a separate Label Improvement Program.

## B. Use Profile

Butylate is a selective herbicide registered solely for use on corn (field, sweet, and popcorn) for control of grassy and broadleaf weeds and nutsedge spp. prior to their emergence. The most common forms of use are applications in combinations with atrazine and/or cyanazine. Butylate formulations include granular forms, emulsifiable concentrates and an encapsulated form. The wettable powder formulation and one of the two granular formulations are sold as package mixes with atrazine.

Butylate is applied with ground equipment and is incorporated into the soil immediately after application. In certain geographic areas, butylate is registered for application into center pivot irrigation systems, injection

into the soil before or at planting, fall application before the ground freezes, or soil application and incorporation between the rows after corn emergence. Butylate is cleared for use with compatible fluid fertilizers and for impregnation on certain dry bulk fertilizer formulations.

## C. Background

Butylate is the common name for the herbicide S-ethyl diisobutyl thiocarbamate ($C_{11}H_{23}NOS$). The Chemical Abstracts designation is S-ethylbis (2-methylpropyl) carbamothioate. The Chemical Abstracts Service (CAS) number is 2008-41-5 and the EPA chemical code number (also known as the Shaughnessy number) is 041405. The trade name for butylate is Sutan. Butylate was first registered in 1967 by the Stauffer Chemical Company.

## D. Regulatory Position

Based on a review and evaluation of all available data and other relevant information on butylate, the Agency has made the following determinations:

1. Manufacturing-use pesticide products containing butylate may be registered for sale, distribution, and use, subject to the terms and conditions specified in this Standard.

2. Available data do not show that any of the risk criteria listed in Section 162.11(a) of Title 40 of the U.S. Code of Federal Regulations have been met or exceeded for the uses of butylate specified in this Standard. However, gaps in the data base prevent the completion of the Agency's risk assessment on this chemical.

3. Registrants must provide or agree to develop additional data, as specified in Tables A and B attached to this guidance document, in order to maintain existing registrations or to permit new registrations of substantially similar butylate MPs.

4. Applications of the pesticide butylate made in accordance with the current use directions are not expected to result in residues of butylate in excess of the established tolerance of 0.1 part per million for corn grain (including popcorn), fresh corn (including sweet corn - kernels plus cob with husk removed), and corn forage and fodder (including sweet corn, field corn and popcorn). Butylate is rapidly and completely metabolized in corn to carbon dioxide and to fragments which are incorporated into naturally occurring plant constituents. Therefore, no metabolites have been included in the tolerance. No tolerances have been set for butylate or its metabolites in milk, meat or meat byproducts, because no residues are expected in feed. For the same reasons, no storage and stability data are required.

E. Regulatory Rationale

The Agency will continue to allow the registration of butylate, for the following reasons:

1. Available toxicological data indicate that technical butylate has low oral, dermal, and dermal irritation toxicities. Technical butylate is classified under Toxicity Category III for these tests. It has moderate primary eye irritation toxicity, and falls under Toxicity Category II for that type of toxicity.

Subchronic (three-week) dermal tests on rabbits showed no systemic effects at 20 and 40 mg/kg. In a 21-day subchronic rat feeding study, no hematological effects, nor gross organ damage was observed at doses up to 32 mg/kg. Dogs fed technical butylate in a 13-week subchronic study showed no effects on behavior or body weight, nor were any effects seen on their neurological, opthalmological, or hematological systems, blood chemistry, or brain AChE. There were no mortalities and no gross changes in organ weight or appearance.

In a 56-week feeding study on rats, doses of 10 and 30 mg/kg produced no major effects, though blood clotting parameters were affected at the lowest dose tested, 10 mg/kg. At Highest Dose Tested (HDT) 180 mg/kg, researchers noted liver perichologitis, and uterine and testicular changes with focal hemorrhages.

A two-year feeding study on mice showed no effects at 20 mg/kg/day, and found no dose-related oncological effects at any dose level tested, including the HDT of 320 mg/kg/day. A teratological study on mice showed no maternal effects, and no fetal effects among natural or caesarian births at doses up to 24 mg/kg.

2. It is not the Agency's policy to cancel or withhold registration solely because of data gaps. (See Sections 3(C)(2)(b) and 3(C)7 of the FIFRA.) In fact, the Registration Standards process is one means of identifying data needs. The data requested by the Agency will be reviewed and evaluated as it is received, and the Agency will determine whether any of the submissions affect existing or potential registrations of butylate.

3. Butylate is practically non-toxic to birds, whether injested as an acute dose or in subacute feeding studies. The acute oral $LD_{50}$ of technical butylate to mallard ducks is greater than 4,640 mg/kg, and the 8-day dietary $LC_{50}$ to bobwhite quail is estimated to be 40,000 ppm.

   Butylate is only slightly toxic to aquatic invertebrates, with a 48-hr $LC_{50}$ of 11.9 ppm. It is at least moderately toxic to both warmwater and coldwater fish, but the additional requested data may show a greater toxicity. Until the Agency receives more definitive fish acute studies and a more complete environmental fate profile, the potential hazards to fish populations that result from the registered uses cannot be fully assessed.

4. Data to support the establishment of reentry protection standards are not required because the Agency has determined, based on the use patterns and available toxicology data, that the criteria in §158.140 have not been met.

F. Criteria for Registration Under This Standard

To be covered by this Standard, products must:

- o be a manufacturing use product containing butylate as the sole active ingredient,

- o bear required labeling and conform to the product composition, acute toxicity limits, and use pattern requirements listed in Section F of this document.

The applicant for registration or reregistration of products subject to this Standard must comply with all terms and conditions described in it. This includes making a commitment to fill data gaps on a schedule specified by the Agency. Applicants for registration under this Standard must follow the instructions contained in this guidance package and complete and submit the appropriate forms within the time specified.

G. Acceptable Ranges and Limits

1. Product Composition Standard

Technical grade products must contain at least 93 percent butylate as the sole active ingredient. Each manufacturing-use product formulation proposed for registration must be fully described with an appropriate certification of limits. In addition, the active ingredient found in the manufacturing-use butylate products must be substantially similar to that in currently registered technical products. Any manufacturing-use product not meeting these requirements will be considered a new product and will not be registered under this standard.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing butylate when the appropriate acute toxicity categories are no higher than Category II. The labeling of any registered products must bear the appropriate precautionary statements.

3. Use Patterns

To be registered under this Standard, manufacturing-use products containing butylate must be labeled for formulation into end-use products that are to be used for the control of grassy weeds, broadleaf weeds, and/or nutsedge spp. in corn (field, sweet, and/or popcorn).

H. Required Labeling

All technical grade and manufacturing-use products containing butylate must bear appropriate labeling as specified in 40 CFR 162.10. Other portions of the guidance package contain specific information regarding label requirements. In addition, the following specific labeling requirements apply to technical and manufacturing-use products:

1. Use Pattern Statements

"For formulation into end-use herbicide products intended only for use on corn."

2. Precautionary Statements

Environmental Hazard Statement

"Do not discharge into lakes, streams, ponds, or public waters unless in accordance with a NPDES permit. For guidance contact your regional office of the EPA."

The following specific labeling requirements apply to the end-use products:

"Do not apply directly to water or wetlands. Do not contaminate water by cleaning of equipment or disposal of wastes. Cover or incorporate spills."

After review of data to be submitted under this Standard, the Agency may impose additional label requirements.

I. Tolerance Reassessment

A tolerance reassessment has been conducted by the Agency. The Agency has concluded that no tolerance changes are needed at this time. There exists adequate data to support the existing tolerance for residues of butylate for corn grain (including popcorn), fresh corn (including sweet corn - kernels plus cob with husks removed), and corn forage and fodder (including sweet corn, field corn and popcorn) at 0.1 part per million.

At present, the establishment of a crop group tolerance is not appropriate, at any level, for the cereal grains group. Additional data would be required if a registrant wishes to establish a crop group tolerance.

The Theoretical Maximum Residue Concentration (TMRC) calculated from existing tolerances is 0.0038 mg/day for 1.5 kg diet/day for a 60 kg human.

# S-ETHYL DIISOBUTYLTHIOCARBAMATE*

041405

TYPE PESTICIDE: Herbicide

FORMULATIONS: G (1%, 1.33%, 10%, 18%); WP (36%); Mcap (4 lb/gal); EC (6 lb/gal, 6.7 lb/gal, 7 lb/gal, 85.1%)

GENERAL WARNINGS AND LIMITATIONS: A selective herbicide that controls grasses and certain broadleaf weeds by interfering with normal germination and seedling development. Established weeds are not controlled. All weed growth and crop stubble should be thoroughly worked into the soil before treatment. Use only on mineral soils (those containing less than 10 percent organic matter). Do not use in AZ or the 10 southernmost CA counties, except for Kern county, where field and silage corn may be treated. The chemical must be incorporated into the soil, applied subsurface, or added in the irrigation water using a center pivot sprinkler. Incorporation should immediately follow application. If possible, apply and incorporate in the same operation. Soil should be well worked and dry enough to permit good incorporation. In irrigated areas, do not apply before pre-irrigation. For preplant applications, plant seed at a maximum depth of 2 inches within 2 weeks of treatment. Do not cultivate deeper than one-half the depth of incorporation or injection. Unless otherwise specified, apply the microencapsulated, emulsifiable concentrate, and wettable powder formulations in 10 to 50 gallons of water per acre. Reduce dosage in proportion to band area actually treated.

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Not located.

PHYTOTOXICITY TO CROPS: Not located.

MODE OF ACTION: Inhibits cell division and growth in the meristematic regions of the plant.

BROADLEAF WEEDS CONTROLLED:

| | |
|---|---|
| @PBDAEBA | common lambsquarters |
| @PEDADBA | common purslane |
| @PEMAEBB | florida pusley |
| @PAFACBI | redroot pigweed |
| @PBGAFBL | tall morningglory |
| @PDAABBB | velvetleaf |

GRASSES AND OTHER MONOCOTS CONTROLLED:

| | | |
|---|---|---|
| @PCABHBB | barnyardgrass | (c) |
| @PCAAZBA | bermudagrass | |
| @PCAAUBA | buffalograss | |

List continued on the next page.

*Butylate
Sutan

GRASSES AND OTHER MONOCOTS CONTROLLED (continued)

| | | |
|---|---|---|
| @PCAAWBF | cenchrus pauciflorus | (b) |
| @PCACWBF | chickencorn | |
| @PCABFAA | crabgrass | |
| @PCACEBD | fall panicum | |
| @PCACUBA | giant foxtail | |
| @PCABIBA | goosegrass | |
| @PCACUBF | green foxtail | |
| @PCACWBC | johnsongrass | (a) |
| @PCACWBG | johnsongrass (seedling) | (b) |
| @PBMADBM | purple nutsedge | (b)(c) |
| @PCACWBB | shattercane | (b) |
| @PCACWBE | sorghum (volunteer) | (b) |
| @PCACEBL | texas panicum | (b) |
| @PCACUBD | yellow foxtail | |
| @PBMADBI | yellow nutsedge | (b)(c) |

(a) Partial control.
(b) Cultivation is also recommended in fields of moderate to heavy weed infestations.
(c) Existing stands must be turned under and thoroughly chopped up before treatment.

S-ETHYL DIISOBUTYLTHIOCARBAMATE

| | Site, Dosage and Formulation (lb a.i./A) | Tolerance, Use, Limitations |
|---|---|---|
| = | AGRICULTURAL CROPS | |
| /2800600 | Corn, Field and/or Silage | 0.1 ppm (grain)<br>0.1 ppm (forage and fodder)<br>0.1 ppm (fresh corn including sweet corn (kernels plus cob with husk removed))<br>General Information: Do not use on corn seed stock. |
| | — | AL state labels<br>Registration Number 006735-05532<br>Registration Number 006735-05533<br>Formulated with S-ethyl diisobutylthiocarbamate. |
| F | | |
| | | Registration Number 006735-05336<br>Formulated with S-ethyl diisobutylthiocarbamate. |
| F | | |
| | | GA state label<br>Registration Number 037914-09441 |
| $2800602<br>&106.7012 | 3.98<br>(6.7 lb/gal EC) | Preplant. Soil incorporation. Broadcast or band. Use the lower dosage on light soils. Use the higher dosage on medium to heavy soils, on all soils for buffalograss and texas panicum control, and on all soils (except blow sands) for moderate to heavy infestations of shattercane, sandbur or nutsedge. |
| &107.0012 | 3.06-3.94<br>(7 lb/gal EC) | |
| &010.0004<br>&104.0009<br>&106.0012 | 3.00-4.00<br>(10% G)<br>(4 lb/gal Mcap)<br>(6 lb/gal EC) | |
| I9900300<br>&106.7012 | 3.98-6.14<br>(6.7 lb/gal EC) | Preplant. Soil incorporation. Broadcast or band. Bermudagrass, buffalograss, johnsongrass, nutsedge, shattercane and texas panicum control. Use the higher dosage for medium to heavy soils, heavy infestations, shattercane control, and rhizome johnsongrass suppression. May be tank mixed with atrazine and related compounds; 2-((4-chloro-6-(ethylamino)-s-triazin-2-yl)amino)-2-methylpropionitrile; or atrazine and related compounds and 2-((4-chloro-6-(ethylamino)-s-triazin-2-yl)amino)-2-methylpropionitrile. |
| &104.0009 | 4.00-6.00<br>(4 lb/gal Mcap) | |

| | Site, Dosage and Formulation (lb a.i./A) | Tolerance, Use, Limitations |
|---|---|---|
| | **Corn, Field and/or Silage** (continued) | |
| &106.0012 | 3.00-3.90 (6 lb/gal EC) | Preplant. Soil incorporation. Broadcast or band. Use the higher dosage on clay soils with more than 4 percent organic matter, and on all soil types (except sands and loamy sands of less than 1 percent organic matter and the light sandy soils of the Eastern Coastal States) for cenchrus pauciflorus, nutsedge, shattercane and texas panicum control. Follow with a preemergence application of 2-((4-chloro-6-(ethylamino)-s-triazin-2-yl)-amino)-2-methylpropionitrile. |
| I9900300 &106.0012 | 3.00-3.90 (6 lb/gal EC) | Preplant. Soil incorporation. Broadcast or band. Tank mix with atrazine and related compounds; 2-((4-chloro-6-(ethyl-amino)-s-triazin-2-yl)-amino)-2-methylpropionitrile; or atrazine and related compounds and 2-((4-chloro-6-(ethyl-amino)-s-triazin-2-yl)amino)-2-methylpropionitrile. Use the higher dosage on all soil types (except sands and loamy sands of less than 1 percent organic matter and the light sandy soils of the Eastern Coastal States) for cenchrus pauciflorus, nutsedge, seedling johnsongrass, shattercane and texas panicum control. |
| &106.7012 | 3.14-3.98 (6.7 lb/gal EC) | |
| I9900300 &106.7012 | 6.14 (6.7 lb/gal EC) | Use limited to IA (north of Interstate 80), IL (north of Interstate 80), MN, NE (north of Interstate 80 and east of State Highway 14), SD (east of the Missouri River) and WI. Preplant. Soil incorporation. Broadcast or band. Apply in late fall. Do not use for shattercane control. May be tank mixed with atrazine and related compounds. |
| &010.0004 | 3.00-4.00 (10% G) | Use limited to the midwestern and northcentral corn growing regions. Preplant. Soil incorporation. Broadcast or band. Use the lower dosage on blow sands. Use the higher dosage on all soils (except blow sands) for moderate to heavy infestations of nutsedge and shattercane. |
| &107.0012 | 3.94 (7 lb/gal EC) | |
| I9900300 &106.0012 | 3.00-4.00 (6 lb/gal EC) | Preplant. Soil incorporation. Broadcast or band. Tank mix with atrazine and related compounds. Use the higher dosage on clay soils with over 5 percent organic matter, for buffalograss control, and for moderate to heavy infestations of nutsedge and shattercane on all soil types (except blow sands, and the light sandy soils of the Eastern Coastal States). |
| &107.0012 | 3.06-3.94 (7 lb/gal EC) | |

S-ETHYL DIISOBUTYLTHIOCARBAMATE

| | Site, Dosage and Formulation (lb a.i./A) | Tolerance, Use, Limitations |
|---|---|---|
| | **Corn, Field and/or Silage** (continued) | |
| F<br>&018.0004<br>&036.0006 | 3.00-4.08<br>(18% G)<br>(36% WP) | Use limited to the midwestern, northcentral and northeastern corn growing regions. Preplant. Soil incorporation. Broadcast or band. Apply immediately, or up to 2 weeks before planting. Use the higher dosage on clay soils with over 5 percent organic matter, and for moderate to heavy infestations of nutsedge and shattercane on all soil types (except blow sands and the light sandy soils of the Eastern Coastal States). Formulated with atrazine and related compounds. |
| F<br>&018.0004<br>&036.0006 | 3.00<br>(18% G)<br>(36% WP) | Use limited to all corn growing regions other than the midwestern, northcentral and northeastern regions. Preplant. Soil incorporation. Broadcast or band. Apply immediately, or up to 2 weeks before planting. Formulated with atrazine and related compounds. |
| &106.0012 | 4.00<br>(6 lb/gal EC) | Use limited to the midwestern, northcentral and southwestern corn growing regions. Preplant. Soil incorporation. Broadcast or band. Buffalograss and texas panicum control. |
| &106.0012 | 3.00<br>(6 lb/gal EC) | Use limited to the Southeastern United States. Preplant or at planting. Subsurface application. Broadcast or band. Inject 3 inches below the soil surface. |
| &106.7012 | 3.14<br>(6.7 lb/gal EC) | |
| &107.0012 | 3.06<br>(7 lb/gal EC) | Use limited to the midwestern, northcentral and northeastern corn growing regions. Preemergence. Soil incorporation. Broadcast or band. Use if local conditions made a preplant application unfeasible. |
| F<br>&036.0006 | 3.00<br>(36% WP) | Use limited to the midwestern, northcentral and northeastern corn growing regions. Preemergence. Soil incorporation. Broadcast or band. Incorporate to a depth of 1 to 1.5 inches. Formulated with atrazine and related compounds. |
| F<br>&018.0004 | 3.00<br>(18% G) | Use limited to IA, KS, MN, ND, NE and SD. Preemergence. Soil incorporation. Incorporate to a depth of 1 to 1.5 inches. Formulated with atrazine and related compounds. |

S-ETHYL DIISOBUTYLTHIOCARBAMATE

| | Site, Dosage and Formulation (lb a.i./A) | Tolerance, Use, Limitations |
|---|---|---|
| | Corn, Field and/or Silage (continued) | |
| $2800603<br>&106.7012<br>I9900300 | 3.98-6.14<br>(6.7 lb/gal EC) | Use limited to the Western Plains States. Preplant or preemergence. Irrigation water treatment. Apply in sufficient water to penetrate the soil to a depth of 5 to 7 inches immediately after the last tillage operation. Meter into the irrigation water during the entire period. Use the lower dosage for annual grass control. Use the higher dosage for medium to heavy soils, heavy infestations, and for shattercane control. May be tank mixed with atrazine and related compounds. |
| I9900300<br>&106.0012<br><br>&106.7012 | 3.00-4.00<br>(6 lb/gal EC)<br><br>3.14-3.98<br>(6.7 lb/gal EC) | Use limited to the Western Plains States. Preplant. Irrigation water treatment. Tank mix with atrazine and related compounds. Apply in sufficient water to penetrate the soil to a depth of 5 to 7 inches immediately after the last tillage operation. Meter into the irrigation water during the entire period. Use the higher dosage for moderate to heavy infestations of cenchrus pauciflorus, nutsedge, seedling johnsongrass, and shattercane on all soil types except blow sands. |
| $2800601<br>&107.0012<br>I9900300 | 3.06<br>(7 lb/gal EC) | Use limited to the midwestern, northcentral and northeastern corn growing regions. Postemergence. Soil incorporation. Broadcast or band. Tank mix with atrazine and related compounds. Use if local conditions made a preplant application unfeasible. Apply up to the 3- to 4-leaf stage. |
| F<br>&036.0006 | 3.00<br>(36% WP) | Use limited to the midwestern, northcentral and northeastern corn growing regions. Postemergence. Soil incorporation. Broadcast or band. Apply up to the 3- to 4-leaf stage. Incorporate to a depth of 1 to 1.5 inches.<br>Formulated with atrazine and related compounds. |

S-ETHYL DIISOBUTYLTHIOCARBAMATE

| | Site, Dosage and Formulation (lb a.i./A) | Tolerance, Use, Limitations |
|---|---|---|
| /1500400 | Corn, Pop | 0.1 ppm (grain)<br>0.1 ppm (forage and fodder)<br>General Information: Do not use on corn seed stock. |
| $1500402<br>&106.7012<br>I9900300 | 3.98-6.14<br>(6.7 lb/gal EC) | Preplant. Soil incorporation. Broadcast or band. Use the lower dosage for annual grass control. Use the higher dosage for medium to heavy soils, heavy infestations, shattercane control, and rhizome johnsongrass suppression. May be tank mixed with atrazine and related compounds; 2-((4-chloro-6-(ethylamino)-s-triazin-2-yl)amino)-2-methylpropionitrile; or atrazine and related compounds and 2-((4-chloro-6-(ethylamino)-s-triazin-2-yl)amino)-2-methylpropionitrile. |
| I9900300<br>&106.7012 | 3.14-3.98<br>(6.7 lb/gal EC) | Preplant. Soil incorporation. Broadcast or band. Tank mix with atrazine and related compounds; 2-((4-chloro-6-(ethylamino)-s-triazin-2-yl)-amino)-2-methylpropionitrile; or atrazine and related compounds and 2-((4-chloro-6-(ethyl-amino)-s-triazin-2-yl)amino)-2-methylpropioni-trile. Use the higher dosage on medium to heavy soils and for cenchrus pauciflorus and seedling johnsongrass control. |
| I9900300<br>&106.7012 | 6.14<br>(6.7 lb/gal EC) | Use limited to IA (north of Interstate 80), IL (north of Interstate 80), MN, NE (north of Inter-state 80 and east of State Highway 14), SD (east of the Missouri River) and WI. Preplant. Soil incorporation. Broadcast or band. Apply in late fall. Do not use for shattercane control. May be tank mixed with atrazine and related compounds. |
| &106.7012 | 3.14<br>(6.7 lb/gal EC) | Use limited to the Southeastern United States. Preplant or at planting. Subsurface application. Broadcast or band. Inject 3 inches below the soil surface. |
| $1500403<br>&106.7012<br>I9900300 | 3.98-6.14<br>(6.7 lb/gal EC) | Use limited to the Western Plains States. Pre-plant or preemergence. Irrigation water treat-ment. Apply in sufficient water to penetrate the soil to a depth of 5 to 7 inches immediately after the last tillage operation. Meter into the ir-rigation water during the entire period. Use the lower dosage for annual grass control. Use the higher dosage for medium to heavy soils, heavy infestations, and for shattercane control. May be tank mixed with atrazine and related compounds. |

S-ETHYL DIISOBUTYLTHIOCARBAMATE

| | Site, Dosage and Formulation (lb a.i./A) | Tolerance, Use, Limitations |
|---|---|---|
| | Corn, Pop (continued) | |
| I9900300 &106.7012 | 3.14-3.98 (6.7 lb/gal EC) | Use limited to the Western Plains States. Preplant or preemergence. Irrigation water treatment. Tank mix with atrazine and related compounds. Apply in sufficient water to penetrate the soil to a depth of 5 to 7 inches immediately after the last tillage operation. Meter into the irrigation water during the entire period. Use the higher dosage on medium to heavy soils and for cenchrus pauciflorus and seedling johnsongrass control. |
| /1500500 | Corn, Sweet | 0.1 ppm (grain)<br>0.1 ppm (forage and fodder)<br>0.1 ppm (fresh corn including sweet corn (kernels plus cob with husk removed))<br>General Information: Do not use on corn seed stock. |
| -- | | AL state labels<br>Registration Number 006735-05532<br>Registration Number 006735-05533<br>Formulated with S-ethyl diisobutylthiocarbamate.<br>Registration Number 006735-05536<br>Formulated with S-ethyl diisobutylthiocarbamate.<br>GA state label<br>Registration Number 037914-09441 |
| F | | |
| F | | |
| $1500502 S2800602 | | Preplant, at planting or preemergence. Refer to Corn, Field and/or Silage for use and limitation information. |
| $1500503 S2800603 | | Preplant or preemergence. Irrigation water treatment. Refer to Corn, Field and/or Silage for use and limitation information. |
| $1500501 S2800601 | | Postemergence. Refer to Corn, Field and/or Silage for use and limitation information. |

S-ETHYL DIISOBUTYLTHIOCARBAMATE

| Site, Dosage and Formulation (lb a.i./A) | Tolerance, Use, Limitations |
|---|---|
| AERIAL AND TANK MIX APPLICATIONS | |
| Tank Mix | |
| -- | Refer to<br>AGRICULTURAL CROPS<br>All sites |

# S-ETHYL DIISOBUTYLTHIOCARBAMATE

## Listing of Registered Pesticide Products by Formulation

&001.0004 # — 1% granular
S-ethyl diisobutylthiocarbamate (041405) plus atrazine and related compounds (080803)
006735-05536

&001.3304 # — 1.33% granular
S-ethyl diisobutylthiocarbamate (041405)
006735-05532

# — S-ethyl diisobutylthiocarbamate (041405) plus atrazine and related compounds (080803)
006735-05533

&010.0004 # — 10% granular
S-ethyl diisobutylthiocarbamate (041405)
000476-02001 002749-00168

&018.0004 # — 18% granular
S-ethyl diisobutylthiocarbamate (041405) plus atrazine and related compounds (080803)
000476-02103

&036.0006 # — 36% wettable powder
S-ethyl diisobutylthiocarbamate (041405) plus atrazine and related compounds (080803)
000476-02024

&104.0009 # — 4 lb/gal microencapsulated
S-ethyl diisobutylthiocarbamate (041405)
000476-02180

&106.0012 # — 6 lb/gal emulsifiable concentrate
S-ethyl diisobutylthiocarbamate (041405)
000476-02000 000476-02132

&106.7012 # — 6.7 lb/gal emulsifiable concentrate
S-ethyl diisobutylthiocarbamate (041405)
000476-02156

&107.0012 # — 7 lb/gal emulsifiable concentrate
S-ethyl diisobutylthiocarbamate (041405)
000476-02049

&285.1012 # — 85.1% emulsifiable concentrate
S-ethyl diisobutylthiocarbamate (041405)
037914-09441

## I. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

A. This portion of the guidance document is a Notice issued under the authority of FIFRA Section 3(c)(2)(B) and describes, in table format, the data required for maintaining the registrability of each product. Additionally, a bibliography (Appendix II-1) is included that identifies that data considered as part of the data base supporting this standard. EPA has determined that additional generic data described in this Notice must be submitted to EPA for evaluation in order to maintain in effect the registration(s) of your product(s) identified as an attachment to the cover letter accompanying this guidance document. As required by FIFRA Section 3(c)(2)(B), you are required to take appropriate steps to comply with this Notice.

EPA may suspend the registration of each of those products unless, within the specified time, you have informed EPA how you will satisfy the requirements of this Notice. Any such suspension will remain in effect until you have complied with the terms of this Notice.

B. What Generic Data 1/ Must Be Submitted. You may ascertain which generic data you must submit by consulting Table A at the end of this chapter. That table shows all the generic data needed to evaluate the continued registrability of all products, and the dates by which the data must be submitted. The required data must be submitted and any necessary studies must be conducted in accordance with EPA-approved protocols, the Pesticide Registration Guidelines 2/, or data collected under the approved protocols of the Organization for Economic Cooperation and Development (OECD). If you wish not to develop data which are necessary to support the registration or reregistration of certain uses appearing in your labeling, you may delete those uses at the time you submit your revised labeling.

Also for certain kinds of testing (generally ecological effects), EPA requires the test substance to be a "typical formulation," and in those cases EPA needs data of that

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1/ Generic data pertain to the properties or effects of a particular ingredient, and thus are relevant to an evaluation of the risks of all products containing that ingredient (or all such products having a certain use pattern), regardless of any such product's unique composition or use. Product-specific data relate only to the properties or effects of a product with a particular composition (or a group of products with closely similar composition).

2/ The Pesticide Registration Guidelines were reproposed on November 24, 1982 in 47 Federal Register 53192.

type for each major formulation category (e.g., emulsifiable concentrates, wettable powders, granulars, etc.) These are classified as generic data and when needed are specified in Table A. EPA may possess data on certain "typical formulations" but not others. Note: The "typical formulation" data should not be confused with product-specific data (Table B) which are required on each formulation. Product-specific data are further explained in Chapter IV of this document.

C. Options Available for Complying With Requirements to Submit Data

Within 90 days of your receipt of this Notice you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" [EPA Form 8580-1, Appendix II-2] for each of your products. On that form you must state which of the following methods you will use to comply with the requirements of this Notice:

1. (a) Notify EPA that you will submit the data, and

   (b) either submit the existing data you believe will satisfy the requirement, or state that you will generate the data by conducting testing. If the test procedures you will use deviate from (or are not specified in) the Registration Guidelines or protocols contained in the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must enclose the protocols you will use.

2. Notify EPA that you have entered into an agreement with one or more other registrants to jointly develop (or share in the cost of developing) the data. If you elect this option, you must notify EPA which registrant(s) are parties to the agreement.

3. File with EPA a completed "Certification of Attempt to Enter Into an Agreement With Other Registrants for Development of Data" (EPA Form 8580-6, Appendix II-3)*/

4. Request that EPA amend your registration by deleting the uses for which the data are needed. (This option is not available to applicants for new products.)

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*/ FIFRA Section 3(c)(2)(B) authorizes joint development of data by two or more registrants, and provides a mechanism by which parties can obtain an arbitrator's decision if they agree to jointly develop data but fail to agree on all the terms of the agreement. The statute does not compel any registrant to agree to develop data jointly.
(Footnote continued at bottom of next page)

5. Request voluntary cancellation of the registration(s) of your products for which the data are needed. (This option is not available to applicants for new products.)

D. Procedures for Requesting Changes in Testing Methodology and Extensions of Time

EPA recognizes that you may disagree with our conclusions regarding the appropriate ways to develop the required data or how quickly the data must be submitted. If the test procedures you plan to use deviate from (or are not specified in) the registration guidelines or protocols contained in the reports of the Expert Groups to the Chemical Groups, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit the protocol for Agency review prior to the initiation of the test.

If you think that you will need more time to generate the required data than is allowed by EPA's schedule, you may submit a request for an extension of time. The extension request must be submitted in writing to the Product Manager. The extension request should state the reasons why you conclude that an extension is appropriate. While EPA considers your request, you must strive to meet the deadline for submitting the required data.

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(Footnote continued from previous page)

In EPA's opinion, joint data development by all registrants who are subject to the requirements to submit a pertinent item of data or a cost-sharing agreement among all such registrants is clearly in the public interest. Duplication of testing could increase costs, tie up testing facilities, and subject an unnecessarily large number of animals to testing.

As noted earlier, EPA has discretion not to suspend the registration of a product when a registrant fails to submit data required under FIFRA Section 3(c)(2)(B). EPA has concluded that it is appropriate to exercise its discretion not to suspend in ways which will discourage duplicative testing. Accordingly, if (1) a registrant has informed us of his intent to develop and submit data required by this Notice; and (2) a second registrant informs EPA that it has made a bona fide offer to the first registrant to share in the expenses of the testing [on terms to be agreed upon or determined by arbitration under FIFRA Section 3(c)(2)(B)(iii)]; and (3) the first registrant has declined to agree to enter into a cost-sharing agreement, EPA will not suspend the second firm's registration. While the first firm is not required to agree to jointly develop data, EPA is not required to force the second firm to engage in economically inefficient duplicative testing in order to maintain its registration.

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/] |
|---|---|---|---|---|
| §158.120 Product Chemistry | | | | |
| Product Identity: | | | | |
| 61-1 - Identity of Ingredients | TGAI | Yes | 00020545<br>00026325<br>00043679<br>00063484 | No |
| 61-2 - Statement of Composition | TGAI | Partial | 00063484 | Yes[3/] |
| 61-3 - Discussion of Formation of Ingredients | TGAI | Partial | 00063484 | Yes[4/] |
| Analysis and Certification of Product Ingredients | | | | |
| 62-1 - Preliminary Analysis | TGAI | Partial | 00063484<br>GS-0071-005 | Yes[3/] |
| 62-2 - Certification of Limits | TGAI | Partial | 00063484 | Yes[5/] |
| 62-3 - Analytical Methods for Enforcement Limits | TGAI | Partial | 00023535<br>00025676<br>00064183<br>05018944<br>GS-0071-001<br>GS-0071-006 | Yes[6/] |

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/] |
|---|---|---|---|---|
| §158.120 Product Chemistry (continued) | | | | |
| Physical and Chemical Characteristics | | | | |
| 63-2 - Color | TGAI | Yes | 00026324<br>00063484<br>Reg. #748-232 | No |
| 63-3 - Physical State | TGAI | Yes | 00020535<br>00026324<br>00063484<br>Reg. #748-232 | No |
| 63-4 - Odor | TGAI | Yes | 00063484<br>Reg. #748-232 | No |
| 63-5 - Melting Point | TGAI | | | |
| 63-6 - Boiling Point | TGAI | Yes | 00063484<br>Reg. #748-232 | No |
| 63-7 - Density, Bulk Density or Specific Gravity | TGAI | Yes | 00021822<br>00063484 | No |
| 63-8 - Solubility | TGAI OR PAI | Yes | 00063484 | No |
| 63-9 - Vapor Pressure | PAI | Yes | 00063484 | No |
| 63-10 - Dissociation constant | PAI | No | -- | Yes[3/] |
| 63-11 - Octanol/water partition coefficient | PAI (pure form) | No | -- | Yes[3/] |

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/] |
|---|---|---|---|---|
| §158.120 Product Chemistry (Continued) | | | | |
| 63-12 - pH | TGAI | Yes | 00026324<br>00063484 | No |
| 63-13 - Stability | TGAI | Yes | 00063484 | No |
| Other Requirements: | | | | |
| 64-1 - Submittal of samples | Choice | -- | -- | --[7/] |

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient. Choice = Choice of several test substances determined on a case-by-case basis.

2/ Data must be submitted no later than 6 months from receipt of Guidance Document.

3/ An updated statement of composition by Stauffer is needed. Better representation is needed in the statement of composition by PPG.

4/ Because of certain differences in the composition of the two products by Stauffer and PPG, additional details on the manufacturing procedures are needed. Stauffer should also indicate the composition of its starting materials. Evidence tht nitrosamines are absent in butylate is needed form both producers.

5/ Declaration and certification of limits is needed.

6/ Validation data for the preliminary methods of analysis are needed.

7/ The Agency will require a sample if the need arises.

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/] |
|---|---|---|---|---|
| §158.125 Residue Chemistry | | | | |
| 171-4 - Nature of Residue (Metabolism) | | | | |
| - Plants | PAIRA | Yes | 00020555<br>00020558<br>00021594<br>00021781<br>00021822<br>00021849<br>GS-0071-003<br>GS-0071-006 | No |
| - Livestock | PAIRA and plant metabolites | N/A | - | No[3/] |
| 171-4 - Residue Analytical Method | | | | |
| - Plant residues | TGAI and metabolites | Yes | 00022848 05002372<br>00023535 05010440<br>00024324 05013158<br>00025676 05018944<br>00063485 GS-0071-001<br>00064183 GS-0071-004<br>00068699 GS-0071-006 | No |
| - Animal Residues | TGAI and metabolites | N/A | - | No[3/] |

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/] |
|---|---|---|---|---|---|
| §158.125 Residue Chemistry (continued) | | | | | |
| 171-4 - Storage Stability Data | PAI | N/A | -- | | No[3/] |
| 171-4 - Magnitude of the Residue-Residue Studies for Each Food Use | | | | | |
| - Crop Group #1 - (Cereal Grains Group) | | | | | |
| o Crop 1 (Corn Grain) | | | | | |
| -- Crop field trials | TEP | Yes | 00020547 | 00023817 | No |
| | | | 00020564 | 00012818 | |
| | | | 00021749 | 00023819 | |
| | | | 00021751 | 00024775 | |
| | | | 00021753 | 00026259 | |
| | | | 00021755 | 00026260 | |
| | | | 00021759 | 00026315 | |
| | | | 00021766 | 00026316 | |
| | | | 00021769 | 00026974 | |
| | | | 00021783 | 00035840 | |
| | | | 00021784 | 00037762 | |
| | | | 00021787 | 00041699 | |
| | | | 00021803 | 00090889 | |
| | | | 00021856 | 00093221 | |
| | | | 00022846 | 00093222 | |
| | | | 00023727 | GS-0071-004 | |
| | | | 00023816 | | |

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/] |
|---|---|---|---|---|
| §158.125 Residue Chemistry (continued) | | | | |
| 171-4 - Magnitude of the Residue-Residue Studies (continued) | | | | |
| --Processed Food/Feed | EP | N/A | -- | No[4/] |
| --Crop Group #2 (Forage, Fodder, and Straw of Cereal Grains Group) | | | | |
| o Crop Field Trials | TEP | Yes | See Citations Under Corn Grain | No |
| -- Meat/milk/poultry/eggs | TGAI or plant metabolites | N/A | -- | No[5/] |

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

§158.125 Residue Chemistry
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product; EP = End-use product.

2/ Data must be submitted no later than N/A

3/ Butylate is rapidly and completely metabolized in corn. Therefore, there is no need for animal metabolism, animal residue, or storage stability data.

4/ Because there are no detectable residues in grain, no residues are expected in byproducts (corn meal and corn oil).

5/ Because no residues are expected to be found in feeds, there can be no transfer of residues to animal and/or poultry products.

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1]/ | Pattern[2]/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]/ |
|---|---|---|---|---|---|
| 158.130 Environmental Fate | | | | | |
| DEGRADATION STUDIES-LAB: | | | | | |
| 161-1 - Hydrolysis | TGAI or PAIRA | A, | No | -- | Yes |
| Photodegradation | | | | | |
| 161-2 - In Water | TGAI or PAIRA | A | No | -- | Yes |
| 161-3 - On Soil | TGAI or PAIRA | A | No[4]/ | -- | No |
| 161-4 - In Air | TGAI or PAIRA | A | N/A | -- | No[6]/ |
| METABOLISM STUDIES-LAB: | | | | | |
| 162-1 - Aerobic Soil | TGAI or PAIRA | A | Yes | 00026320<br>00043683<br>00043684 | No |
| 162-2 - Anaerobic Soil | TGAI or PAIRA | A | Yes | 00043684 | No |
| 162-3 - Anaerobic Aquatic | TGAI or PAIRA | A | N/A[5]/ | -- | No |
| 162-4 - Aerobic Aquatic | TGAI or PAIRA | A | N/A[5]/ | 00027139 | No |

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1]/ | Pattern[2]/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]/ |
|---|---|---|---|---|---|
| 158.130 Environmental Fate (continued) | | | | | |
| MOBILITY STUDIES: | | | | | |
| 163-1 - Leaching and Adsorption/Desorption | TGAI or PAIRA | A | Yes | 00027139<br>00027140<br>00043683 | No |
| 163-2 - Volatility (Lab) | TEP | A | Partially[7]/ | 00043683 | No[6]/ |
| 163-3 - Volatility (Field) | TEP | A | N/A | -- | No[6]/ |
| DISSIPATION STUDIES - FIELD: | | | | | |
| 164-1 - Soil | TEP | A | Partially[8]/ | 00021848<br>00023814 | Yes |
| 164-2 - Aquatic | TEP | A | N/A[9]/ | -- | No |
| 164-3 - Forestry | TEP | A | N/A[9]/ | -- | No |
| 164-4 - Combination and Tank Mixes | | A | N/A[10]/ | -- | No |
| 164-5 - Soil, Long-term | TEP | A | N/A[11]/ | -- | No |

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1]/ | Pattern[2]/ | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3]/ |
|---|---|---|---|---|---|
| 158.130 Environmental Fate | | | | | |
| ACCUMULATION STUDIES: | | | | | |
| 165-1 - Rotational Crops (Combined) | PAIRA | A | No[12]/ | -- | Yes |
| 165-2 - Rotational Crops (Field) | TEP | A | No[12]/ | -- | Yes |
| 165-3 - Irrigated Crops | TEP | A | N/A[13]/ | -- | No |
| 165-4 - Fish | TGAI or PAIRA | A | Partially[14]/ | 00020535 | Yes |
| 165-5 - In Aquatic Non-Target Organisms | TEP | A | N/A[15]/ | -- | No |
| §158.140 Reentry Protection | TEP | A | N/A[16]/ | -- | No |

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

§158.130 Environmental Fate
(continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAIRA = Pure active ingredient, radiolabeled; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Data must be submitted no later than 48 months from receipt of Guidance Document.

4/ No data are required because butylate is soil-incorporated.

5/ No data are required because there are no aquatic uses, forestry uses, or uses likely to have aquatic impacts.

6/ No data are required because there is a minimal probability of exposure by inhalation.

7/ This data requirement may also be satisfied by data that meet the test standards for field volatility studies.

8/ Data are acceptable for parent compound for EC and microencapsulated formulation. Data are needed for two sites for granular and wettable powder and one additonal site for EC and encapsulated formulation. Data must include analyses for degradation products.

9/ Data are not required because there are no aquatic or forestry uses for butylate.

10/ Not applicable to single active ingredient standard.

11/ Information derived from aerobic soil metabolism studies indicate that long-term field dissipation data will not be needed.

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

§158.130 Environmental Fate
(continued)

12/ For crops rotated on treated areas, any one of the following will apply:

(a) A tolerance must be obtained for the rotated crop.

(b) The product label must include a restriction against the rotation of crops used for food or feed on treated areas.

(c) Data must be provided to determine time intervals at which rotated crops planted on treated areas will be free of pesticide residues.

13/ Data are not required because there are no aquatic uses, nor uses in or around holding ponds, nor u involving effluents to water used for crop irrigation. See 165-3(b).

14/ Data on $^{14}C$ residue accumulation in bluegill sunfish are acceptable. Data on chemical identification of residues are required.

15/ No data are required because there are no forestry uses, aquatic uses, or aquatic impact uses that result in direct discharges of treated water into outdoor aquatic sites.

16/ No data are required because worker exposure is not expected to be significant for the uses addressed in this Standard. Based on the use patterns and available toxicology data for butylate, the criteria in §158.40 have not been met.

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1/] | Use Pattern[2/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3/] |
|---|---|---|---|---|---|
| §158.135 Toxicology | | | | | |
| ACUTE TESTING | | | | | |
| 81-1 - Oral $LD_{50}$ - Rat | TGAI | A | Yes | 00063486 | No |
| 81-2 - Dermal $LD_{50}$ | TGAI | A | Yes | 00063486 | No |
| 81-3 - Inhalation $LC_{50}$- Rat | TGAI | A | Partially[4/] | 00063488 | Yes |
| 81-4 - Primary Eye Irritation - Rabbit | TGAI | A | Yes | 00063487 | No |
| 81-5 - Primary Dermal Irritation | TGAI | A | Yes | 00063487 | No |
| 81-6 - Dermal Sensitization | - | - | N/A[5/] | - | No |
| 81-7 - Acute Delayed Neurotoxicity - Hen | - | - | N/A[6/] | - | No |
| SUBCHRONIC TESTING: | | | | | |
| 82-1 - 90-Day Feeding - Rodent, | TGAI | A | Yes | 00035843 | No |
| Non-rodent | None | A | Partially[7/] | 00021846 | Yes |
| 82-2 - 21-Day Dermal | TGAI | A | Yes | 00026312 | No |
| 82-3 - 90-Day Dermal | TGAI | - | N/A[8/] | - | No |
| 82-4 - 90-Day Inhalation - Rat | TGAI | - | N/A[9/] | - | No |
| 82-5 - 90-Day Neurotoxicity- Hen/Mammal | TGAI | - | N/A[10/] | - | No |

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1/] | Use Pattern[2/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3/] |
|---|---|---|---|---|---|
| §158.135 Toxicology (continued) | | | | | |
| CHRONIC TESTING: | | | | | |
| 83-1 - Chronic Toxicity - 2 species: Rodent and Non-rodent | TGAI | A | Partially[11/] | 00035844 | Yes[13/] |
| 83-2 - Oncogenicity Study- 2 species: Rat and Mouse preferred | TGAI | A | Partially[12/] | 00035844 | Yes[13/] |
| 83-3 - Teratogenicity - 2 species | - | - | Partially[14/] | 00026311 | Yes[13/] |
| 83-4 - Reproduction, 2-generation | - | - | No[15/] | - | Yes[13/] |
| MUTAGENICITY TESTING | | | | | |
| 84-2 - Gene Mutation | - | - | No[16/] | - | Yes |
| 84-2 - Chromosomal Aberration | - | - | No[16/] | - | Yes |
| 84-2 - Other Genotoxic Effects | - | - | No[16/] | - | Yes |

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition 1/ | Use 2/ Pattern | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? |
|---|---|---|---|---|---|
| §158.135 Toxicology (continued) | | | | | |
| SPECIAL TESTING | | | | | |
| 85-1 - General Metabolism | TGAI | A | Partially | 00043680<br>00043681<br>00043682 | Yes 17/ |

1/ Composition: Material to be tested is technical grade unless otherwise specified in footnotes.

2/ The use patterns are coded as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.

3/ Unless otherwise specified, data must be submitted no later than 6 months for acute testing, and 48 months for all other testing, from receipt of Guidance Document.

4/ Neither the 1968 study nor the 1980 study was adequate to state that the $LC_{50}$ is greater than 5.0 mg/1. A new study is needed to insure handler safety. The study should establish the inhalation toxicity of butylate to rats, and should include acute exposures at several doses up to 5.0 mg/1. Results should describe observed lethalities, and the gross, general, and histological pathology of all the rats exposed.

5/ Dermal sensitization is required only if repeated contact with human skin in expected to occur. Use of butylate is on corn, once a year, by soil injection. Therefore, normal use should not cause human skins to be repeatedly exposed.

6/ Only organophosphate compounds are tested for acute delayed neurotoxicity.

7/ A non-rodent 90-day study is missing and should be done and submitted to the Agency. There is no chronic non-rodent study that could substitute for this requirement.

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

8/ This 90-day dermal test is required only if pesticide is purposely applied to the skin or it is known that the pesticide is, in fact, metabolized differently in the skin than in the oral route. Neither situation applies here, so the 90-day dermal test is not required for butylate.

9/ Repeated inhalation is not expected, because the pesticide is applied only once a year.

10/ A 90-day neurotoxicity study is required if neuropathy is observed in the acute oral, dermal, and/or inhalation studies, or if the acute delayed neurotoxicity is positive (or a structurally related compound is positive for delayed neurotoxicity). Neither is the case for butylate, so this test is not required.

11/ A chronic mouse study satisfies the rodent requirement, but no non-rodent chronic toxicity study has been submitted.

12/ The Agency has already reviewed a two-year mouse chronic feeding and oncology study (combined) and is currently reviewing a two-year rat study.

13/ In acute oral, inhalation, and subchronic dermal studies, butylate apparently caused congestion in organs that were highly perfused with blood. This pathologic effect should be thoroughly investigated in this study. Tests should also be run for effects on the clotting function and hematology, in order to clearly establish a NOEL. Registrants are advised to submit the protocols to the Agency prior to initiating the study.

14/ The Agency has a rabbit teratology study that was categorized as supplementary data primarily because the doses used were not high enough. This rabbit study should be repeated using higher butylate doses. Furthermore, a species other than the rabbit should be tested for teratogenic effects.

15/ No reproduction studies on butylate have been submitted to the Agency.

16/ No studies submitted. Refer to Pesticide Assessment Guidelines, Subdivision F, Series 84 (1982).

17/ This requirement is almost completed (see review in Butylate Standard, Attachment G). Completion of this requirement entails submission of $^{14}C$-tracer studies on Butylate labeled at the C-1 position in the isobutyl moiety. Both kinetic and organ location with metabolite identification should be done.

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1] | Use Pattern[2] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3] |
|---|---|---|---|---|---|
| §158.145 Wildlife and Aquatic Organisms | | | | | |
| AVIAN AND MAMMALIAN TESTING | | | | | |
| 71-1 - Avian Oral $LD_{50}$ | TGAI | A | Yes | 00025060[9] GS-0071-002[10] | No |
| 71-2 - Avian Dietary $LC_{50}$ | TGAI | A | | | |
| Upland Gamebird | | | Yes | 00021835[9] | No |
| Waterfowl | | | Yes | 00020530[9] | No |
| 71-3 - Wild Mammal Toxicity | TGAI | -- | N/A[5] | - | No |
| 71-4 - Avian Reproduction | TGAI | -- | N/A[6] | - | No |
| 71-5 - Simulated and Actual Field Testing - Mammals and Birds | TEP | -- | N/A[6] | - | No |
| AQUATIC ORGANISM TESTING | | | | | |
| 72-1 - Freshwater Fish $LC_{50}$ | TGAI | A | | | |
| Coldwater Fish | | | Partially | 00021835[10] | Yes[4] |
| Warmwater Fish | | | Partially | 00021835[10] | Yes[4] |
| 72-2 - Acute $LC_{50}$ Freshwater Invertebrates | TGAI | A | Yes | 00021841[9] 05001497[10] | No |

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1/] | Use[2/] Pattern | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3/] |
|---|---|---|---|---|---|
| §158.145 Wildlife and Aquatic Organisms (continued) | | | | | |
| 72-3 - Acute $LC_{50}$ Estuarine and Marine Organisms | TGAI | A | No | - | Reserved[7/] |
| 72-4 - Fish Early Life Stage and Aquatic Invertebrate Life-Cycle | TGAI | A | No | - | Reserved[7/] |
| 72-5 - Fish Life-Cycle | TGAI | A | No | - | Reserved[7/] |
| 72-6 - Aquatic Organism Accumulation | TGAI, PAI or Degradation Product | A | No | - | No[8/] |
| 72-7 - Simulated or Actual Field Testing - Aquatic Organisms | TEP | A | No | - | Reserved[7/] |

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

§158.145 Wildlife and Aquatic Organisms (continued)

1/ Composition: TGAI = Technical grade of the active ingredient; PAI = Pure active ingredient; TEP = Typical end-use product.

2/ The use patterns are coded as follows: A= Terrestrial, Food Crop; B= Terrestrial, Non-Food; C= Aquatic, Food Crop; D= Aquatic, Non-Food; E= Greenhouse, Food Crop; F= Greenhouse, Non-Food; G= Forestry; H= Domestic Outdoor; I= Indoor.

3/ Data must be submitted no later than 48 months from receipt of Guidance Document.

4/ Two fish acute 96-hour $LC_{50}$ tests, one on bluegill sunfish and one in rainbow trout. Available studies reported formation of a precipitate; therefore, the reported $LC_{50}$ values may be higher than in a more definitive study.

5/ Not generally required.

6/ N/A = Not applicable for the purposes of this standard.

7/ Reserved pending receipt of acceptable freshwater fish acute studies and receipt and evaluation of additional environmental fate data.

8/ See Environmental Fate data requirement table (165-4).

9/ Study completely fulfills requirements.

10/ Study must be cited in connection with another study to fulfill requirements.

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition[1/] | Use[2/] Pattern | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[3/] |
|---|---|---|---|---|---|
| §158.155 Nontarget Insect | | | | | |
| NONTARGET INSECT TESTING - | | | | | |
| Polinators: | | | | | |
| 141-1 - Honey bee acute contact $LD_{50}$ | TGAI | A | Yes | 00036935 | No |
| 141-2 - Honey bee toxicity of residues on foliage | TEP | A | N/A[4/] | - | No |
| 141-3 - Wild bees important in alfalfa pollination-toxicity of residues on foliage | TEP | A | N/A[4/] | - | No |
| 141-4 - Honey bee subacute feeding study | [Reserved][5/] | A | | - | |
| 141-5 - Field testing for pollinators | TEP | A | N/A[4/] | - | No |

TABLE A
GENERIC DATA REQUIREMENTS FOR BUTYLATE

| Data Requirement | Composition 1/ | Use 2/ Pattern | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)? 3/ |
|---|---|---|---|---|---|
| §158.155 Nontarget Insect | | | | | |
| NONTARGET INSECT TESTING - AQUATIC INSECTS: | | | | | |
| 142-1 - Acute toxicity to aquatic insects | [Reserved] 6/ | | | | |
| 142-2 - Acute insect life-cycle study | [Reserved] 6/ | | | | |
| 142-3 - Simulated or actual field testing for aquatic insects | [Reserved] 6/ | | | | |
| 143-1 thru 143-3 - NONTARGET INSECT TESTING PREDATORS AND PARASITES | [Reserved] 6/ | | | | |

1/ Composition: TGAI = Technical grade of the active ingredient; TEP = Typical end-use product.
2/ The use pattern codes are as follows: A = Terrestrial, Food Crop; B = Terrestrial, Non-Food; C = Aquatic, Food Crop; D = Aquatic, Non-Food; E = Greenhouse, Food Crop; F = Greenhouse, Non-Food; G = Forestry; H = Domestic Outdoor; I = Indoor.
3/ Data must be submitted no later than N/A
4/ Pesticide tested low in toxicity in first level test. No further testing is required.
5/ Reserved pending development of test methodology.
6/ Reserved pending decision as to whether data requirements should be established.

## III. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Note: This chapter applies only to manufacturing-use products, not end-use products.

A necessary first step in determining which statements must appear on your product's label is the completion and submission to EPA of product-specific data* listed on the form entitled "Product Specific Data Report" (EPA Form 8580-4, Appendix III-1) to fill "gaps" identified by EPA concerning your product. Under the authority of FIFRA Section 3(c)(2)(B), EPA has determined that you must submit these data to EPA in order to register or reregister your product(s). All of these data must be submitted not later than six months after you receive this guidance document.

"Product-Specific Data Requirements for Manufacturing-Use Products" appearing in Table B permit you to determine which product-specific data you must submit. This can be done by examining the entries in the column of those tables entitled "Must Data Be Submitted Under §3(c)(2)(B)."

*/ Product specific data pertains to data that support the formulation which is marketed; it usually includes product chemistry data and acute toxicology data.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING BUTYLATE

| Data Requirement | Composition[1/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/] |
|---|---|---|---|---|
| §158.120 Product Chemistry | | | | |
| Product Identity: | | | | |
| 61-1 - Identity of Ingredients | MP | Yes | 00020545<br>00026325<br>00043679<br>00063484 | No |
| 61-2 - Statement of Composition | MP | Partially | 00063484 | Yes[3/] |
| 61-3 - Discussion of Formation of Ingredients | MP | Partially | 00063484 | Yes[4/] |
| Analysis and Certification of Product Ingredients | | | | |
| 62-1 - Preliminary Analysis | MP | Partially | 00063484<br>GS-0071-005 | Yes[3/] |
| 62-2 - Certification of Limits | MP | Partially | 00063484 | Yes[5/] |
| 62-3 - Analytical Methods for Enforcement of Limits | MP | Partially | 00023535<br>00025676<br>00064183<br>05018944<br>GS-0071-001<br>GS-0071-006 | Yes[6/] |

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING BUTYLATE

| Data Requirement | Composition[1/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/] |
|---|---|---|---|---|
| **Physical and Chemical Characteristics** | | | | |
| 63-2 - Color | MP | Yes | 00026324<br>00063484<br>Reg. #748-232 | No |
| 63-3 - Physical State | MP | Yes | 00020535<br>00026324<br>00063484<br>Reg. #748-232 | No |
| 63-4 - Odor | MP | Yes | 00063484<br>Reg. #748-232 | No |
| 63-7 - Density, bulk density, or specific gravity | MP | Yes | 00063484<br>Reg. #748-232 | No |
| 63-12 - pH | MP | Yes | 00021811<br>00026324<br>00063484 | No |
| 63-14 - Oxidizing or Reducing Action | MP | No | - | Yes |
| 63-15 - Flammability | MP (for combustible liquid only) | Yes | Reg. #748-232 | No |
| 63-16 - Explodability | MP | No | - | Yes |
| 63-17 - Storage Stability | MP | Yes | 00063484<br>Reg. #748-232 | No |

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING BUTYLATE

| Data Requirement | Composition[1/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/] |
|---|---|---|---|---|
| §158.120 Product Chemistry (continued) | | | | |
| 63-18 - Viscosity | MP(for liquid products | Yes | Reg. #748-232 | Yes |
| 63-19 - Miscibility | MP (for emulsifiable liquid products) | No | - | Yes |
| 63-20 - Corrosion | MP | Yes | Reg. #748-232 | No |
| Other Requirements | | | | |
| 64- 1 - Submittal of Samples | Choice | -- | -- | --[7/] |

This table reflects the status of data requirements for the MP of PPG Industries, Inc., which is equivalent to the TGAI (see Table A). All of the requirements of this table would apply to a new MP.

1/ Composition: MP = Manufacturing-use product; Choice = Choice of several test substances determined on a case-by-case basis.
2/ Data must be submitted no later than 6 months from receipt of Guidance Document.
3/ An updated statement of composition by Stauffer is needed. Better representation is needed in the statement of composition by PPG.
4/ Because the Stauffer and PPG products have different compositions, the Agency requires additional details on the manufacturing procedures. Stauffer should also indicate the composition of its starting materials. The Agency also needs evidence from both producers that nitrosamines are absent in butylate.
5/ Declaration and certification of limits is needed.
6/ Validation data for the preliminary methods of analysis are needed.
7/ The Agency will require a sample later if the need arises.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING BUTYLATE

| Data Requirement | Composition[1/] | Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially) | Bibliographic Citation | Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?[2/] |
|---|---|---|---|---|
| §158.135 Toxicology | | | | |
| ACUTE TESTING | | | | |
| 81-1 - Oral $LD_{50}$ - Rat | MP | Yes | 00063486 | No |
| 81-2 - Dermal $LD_{50}$ | MP | Yes | 00063486 | No |
| 81-3 - Inhalation $LC_{50}$ - Rat | MP | Yes | 00063488 | Yes |
| 81-4 - Primary Eye Irritation - Rabbit | MP | Partially | 00063487 | No |
| 81-5 - Primary Dermal Irritation | MP | Yes | 00063487 | No |
| 81-6 - Dermal Sensitization | MP | N/A | - | No |

1/ Composition: MP = Manufacturing-use product.

2/ Data must be submitted no later than 6 months from receipt of Guidance Document.

## IV. SUBMISSION OF REVISED LABELING AND PACKAGING INFORMATION

Note: This chapter applies only to manufacturing-use products, not end-use products.

The Agency requires applicants for registration or reregistration to ensure that each label (1) contains accurate, complete, and sufficient instructions and precautions, reflecting the results of data concerning the product and its ingredients, and (2) incorporates labeling format and terminology which are sufficiently standardized to avoid user confusion.

As part of your application, you will be required to submit draft labeling consistent with: applicable product-specific data; the precautionary statements and use directions; and the regulations concerning classification [40 CFR §162.11(c)], packaging [40 CFR §162.16], and labeling [40 CFR §162.10], as indicated by the following paragraphs of this chapter of the guidance document.

You will be informed later when you must submit the revised labeling set forth in this guidance package.

### A. Label Contents

40 CFR §162.10 requires that certain specific labeling statements must appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to Tables D, E, and F (Appendix IV-2).

Item 1. PRODUCT NAME - The name, brand, or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading. [40 CFR §162.10(b)]

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text. [40 CFR §162.10(c)]

Item 3. NET CONTENTS - A net content statement is required on all labels. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be stated in terms of weight, expressed as avoirdupois pounds

and ounces, and stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces." In addition to the required units specified, net contents may be expressed in metric units. [40 CFR §162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR §162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR §162.10(f)]

Item 6. INGREDIENT STATEMENT - An ingredient statement is required on the front panel and must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredient statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6A. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - All labels are required to have precautionary statements grouped together on the front panel, preferably within a block outline. The table below shows the minimum type size requirements on various size labels, as set forth in the Regulations.

| Size of Label on Front Panel in Square Inches | Signal Word as Required Minimum Type Size All Capitals | "Keep Out of Reach of Children" as Required |
|---|---|---|
| 5 and under | 6 point | 6 point |
| above 5 to 10 | 10 point | 6 point |
| above 10 to 15 | 12 point | 8 point |
| above 15 to 30 | 14 point | 10 point |
| over 30 | 18 point | 12 point |

Item 7A. CHILD HAZARD WARNING STATEMENT - All labels are required to have the statement "Keep Out of Reach of Children" located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR §162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (Caution, Warning, or Danger) is required on the front panel immediately below the child hazard warning statement. [40 CFR §162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, inhalation, or dermal toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word poison. [40 CFR §162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR §162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR §162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements as listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR §162.10 (h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions taken to avoid accident, injury or damage. [40 CFR §162.10 (n)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR §162.10(n)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD

1. Flammability statement. Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in Appendix IV-3. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

2. Criteria for declaration of non-flammability. The following criteria will be used to determine if a product is non-flammable:

   a. A "non-flammable gas" is a gas (or mixture of gases) that will not ignite when a lighted match is placed against the open cylinder valve.

   b. A "non-flammable liquid" is one having a flashpoint greater than 350°F (177°C) as determined by the method specified in 40 CFR §163.61-8(c)(13)(ii) of Subpart D.

   c. A "non-flammable aerosol" is one which meets the following criteria:

      i. The flame extension is zero inches, using the method specified in 40 CFR §163.61-8(c)(13)(ii);

      ii. There is no flash back; and

      iii. The flashpoint of the non-volatile liquid component is greater than 350°F (177°C), determined by the method specified in 40 CFR §163.61-8(c)(13)(i).

3. Declaration of non-flammability. Products which meet the criteria for non-flammability specified above may bear the notation "non-flammable" or "nonflammable (gas, liquid, etc.)" on the label.

   It may appear as a substatement to the ingredients statement, or on a back or side panel, but shall not be highlighted or emphasized (as with an inordinately large type size) in any way that may detract from precaution.

4. Other physical/chemical hazard statements. When chemistry data submitted in accordance with 40 CFR §163.61-10(c) demonstrate hazards of a physical or chemical nature other than flammability, appropriate statements of hazard will be prescribed. Such statements may address hazards of explosivity, oxidizing or reducing capability, or mixing with other substances to produce toxic fumes.

Item 9. MISUSE STATEMENT - The following statement is required on your label: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." [40 CFR §162.10(1)(2)(ii)]

Item 10A. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. Make certain that the statement you use pertains specifically to your product. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix IV-5 for the latest specific storage and disposal product label statements.

Item 10B. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR §162.10]

B. Collateral Information

Bulletins, leaflets, circulars, brochures, data sheets, flyers, and other graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

## V. INSTRUCTIONS FOR SUBMISSION

All applications prepared in response to this Notice should be addressed as follows:

Mr. Robert J. Taylor, Product Manager
Registration Division (TS-767)
Office of Pesticide Programs
Environmental Protection Agency
Washington, D.C. 20460
Phone No. (703) 557-1800

For each product for which continued registration is desired:

1. Within 90 days from receipt of this document, you must submit the "FIFRA Section 3(c)(2)(B) Summary Sheet" EPA Form 8580-1. Refer to Appendix II-2 with appropriate attachments.

2. Within 6 months from receipt of this document registrants must submit:

   a. Confidential Statement of Formula, EPA Form 8570-4.

   b. Product Specific Data Report, EPA Form 8580-4 (Appendix III-1).

   c. Two copies of any required product-specific data.

3. Within the time set forth in Table A, all generic data must be submitted by the affected registrant(s).

Note: If for any reason any required test is delayed or aborted so that meeting the agreed submission time will be delayed, notify the Product Manager listed above.

You will be informed at a later date when you must submit your Application for Amended Pesticide Registration (EPA Form 8570-1) and the revised labeling set forth in this guidance package.

## Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author.

When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library," followed by an alphabetic suffix which

shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

00020530 Hall, A.; Henderson, L. Joiner, R.; et al. (1974) Sutan + 6-E: Safety Evaluation by a Five-Day Feeding Test in Mallard Ducks: T-46444. (Unpublished study received Aug. 29, 1974 under 476-2132; submitted by Stauffer Chemical Co., Richmond, Calif; CDL:026623-A)

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00020545 Stauffer Chemical Company (19??) Basic Manufacturing Process of Sutan Technical. (Unpublished study received Apr. 8, 1976 under 476-2180; CDL:224137-A)

00020547 Sweet, R.; Ilnicki, R.; Johns, R.D.; et al. (1975) Summary of Crop Residue Data for Sutan + 4-S, Sutan + 4-S/Atrazine and Sutan + 4-S/Bladex Tank Mixes on Corn. (Unpulished study received on unknown date under 5E1587; prepared in cooperation with Rutgers, the State Univ. of New Jersey, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:097088-C)

00020555 Fang, S.C. (1969) Thiolcarbamates. Pages 147-164, in Degradation of Herbicides. By P.C. Kearney and D.D. Kaufman. New York: ? (Also in unpublished submission received Mar. 27, 1972 under unknown admin. no.; submitted by Stauffer Chemical Co., Richmond Calif.; CDL:120329-C)

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00021784 Staniforth, D; Heikes, G. (1973) Supportive Residue Data for Bladex(R) Herbicide Tank Mix Combination with Sutan(R) Herbicide. (Unpublished study received Jul 11, 1973 under 201-279; prepared in cooperation with Iowa State Univ. and others, submitted by Shell Chemical Co., Washington, D.C.; CDL:000984-A)

00021787 Illnicki, R.; Brown, R.W. (1964) Crop Residue Report: FSDS No. 3835. (Unpublished study including FSDS nos. 3910 and 3946, received Jan 17, 1966 under unknown admin. no., prepared in cooperation with Pioneer Hi Bred Seed Co., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:123637)

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00021822 Stauffer Chemical Company (19??) Comparative Plant and Animal Metabolism, and Fish and Wildlife Toxicity Data for Eptam(R), Sutan(R), Tillam(R) and Vernam(R). (Unpublished study received Mar 27, 1972 under unknown admin. no.;CDL:120329-A)

00021835 Knott, W.; Beliles, R.P. (1967) R-1910 and R-1910 6-E Safety Evaluation on Fish and Wildlife (Bobwhite Quail, Rainbow Trout, and Bluegill Sunfish). (Unpublished study received Mar 27, 1972 under unknown admin. no.; prepared by Woodard Research Corp., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:120329-T)

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00023727 Dorn, R.W. (1974) Compatibility of Bladex(R) Herbicide with Commercial Herbicide and Liquid Fertilizers. (Unpublished study received Mar 28, 1975 under 201-281; submitted by Shell Chemical Co., Washington, D.C.; CDL:009627-A)

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00024775 Hoffman, L.; Doebler, T.; Parson, W.; et al. (1976) Summary: Sutan + Atrazine 18-6G: residue Data. (Unpublished study received Jan. 29, 1976 under 476-2103; submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:223262-A)

00025060 Fink, R. (1976) Final Report: Acute Oral $LD_{50}$ -- Mallard Duck: Project No. 144-104. (Unpublished study received Apr. 25, 1978 under 476-2180; prepared by Wildlife International, Ltd., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:233577-B

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00026259 Hiddleson, L.M.; Shriver, J.; Conner, B.J.; et al. (1974) To Evaluate Weed Control Performance and Crop Tolerance of Several Herbicides: Test No. NE OH 505 72. (Unpublished study including test nos. NE OH 505 72, MW OH 427 73, NE OH 208 72..., received Apr. 29, 1976 under 100-523; submitted by Ciba-Geigy Corp., Greensboro, N.C.: CDL:224759-A)

00026260 Dowler, C.; Moyer, R.; Kolwaite, R.: et al. (1975) Summary of Crop Residue Data for Sutan 4-S/Atrazine and Sutan 4-S/Bladex Tank Mixes on Corn. (Unpublished study received Jan. 6, 1976 under 476-2180; prepared in cooperation with Agrico Chemical Co., submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:224369-C)

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00026316 Brown, R.W.; Raleigh, S.M.; Noll, C.J.; et al. (1967) Corn Residue Studies. (Unpublished study received Aug. 17, 1967 under 7F0621; prepared in cooperation with Pennsylvania State Univ. and others, submitted by Stauffer Chemical Co., Richmond, Calif; CDL:090812-M)

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00026324 Stauffer Chemical Company (19??) Sutan(R); Chemical and Physical Properties. (Unpublished study received June 26, 1967 under 7F0621; CDL:092915-C)

000026325 Smith, W.J.; Below, J.F. (1967) The Analysis of Technical Sutan and Its Formulations: Report No. RR-67-27. Rev. Three undated methods. (Unpublished study received June 26, 1967 under 7F0621; CDL:092915-D)

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GS-0071-002 Schafer, E.W. (1972) The Acute Oral Toxicity of 369 Pesticidal, Pharmaceutical, and Other Chemicals to Wild Birds. Toxicity and Applied Pharmacology, 21: 315-320.

GS-0071-003 Gray, R.A. and Tomlinson, G.A. (1967) Metabolism of Radioactive S-Ethyl Diisobutylthiocarbamate (Sutan) in Corn and Rats. (Unpublished study received Jul 20, 1967 under 7F0621, submitted by Stauffer Chemical Co., Richmond, Calif.; CDL:RCB-115139.)

GS-0071-004 Stauffer Chemical Company (1967) Results of Test on the Amount and Nature of the Residue, and the Analytical Methodology (Unpublished study received Jul 20, 1967 under 7F0621; CDL:RCB-115140.)

GS-0071-006 Stauffer Chemical Company; Correspondence file for Pesticide Petition No. 7F0621; CDL:RCB-115142.

OMB Approval No. 2000-0468 (Expires 12-31-83)

| FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET | EPA REGISTRATION NO. |
|---|---|
| PRODUCT NAME | |
| APPLICANT'S NAME | DATE GUIDANCE DOCUMENT ISSUED |

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

| REGISTRANT'S AUTHORIZED REPRESENTATIVE | SIGNATURE | DATE |
|---|---|---|
| | | |

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

**CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA**

*(To qualify, certify ALL four items)*

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

| NAME OF FIRM | EPA COMPANY NUMBER |
|---|---|
| | |
| | |
| | |
| | |

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

| NAME OF FIRM | DATE OF OFFER |
|---|---|
| | |
| | |
| | |
| | |

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

| TYPED NAME | SIGNATURE | DATE |
|---|---|---|
| | | |

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Registration No._____ Guidance Document for_____

Date_____

| Registration Guideline No. | Name of Test | Test not required for my product listed above (check below) | I am complying with data requirements by | | (For EPA Use Only) Accession Numbers Assigned |
|---|---|---|---|---|---|
| | | | Citing MRID# | Submitting Data (Attached) | |
| §158.20 PRODUCT CHEMISTRY | | | | | |
| 61-1 | Identity of ingredients | | | | |
| 61-2 | Statement of composition | | | | |
| 61-3 | Discussion of formation of ingredients | | | | |
| 62-1 | Preliminary analysis | | | | |
| 62-2 | Certification of limits | | | | |
| 62-3 | Analytical methods for enforcement limits | | | | |
| 63-2 | Color | | | | |
| 63-3 | Physical state | | | | |
| 63-4 | Odor | | | | |
| 63-5 | Melting point | | | | |
| 63-6 | Boiling point | | | | |
| 63-7 | Density, bulk-density, or specific gravity | | | | |
| 63-8 | Solubility | | | | |
| 63-9 | Vapor pressure | | | | |
| 63-10 | Dissociation constant | | | | |
| 63-11 | Octanol/water partition coefficient | | | | |
| 63-12 | pH | | | | |
| 63-13 | Stability | | | | |
| 63-14 | Oxidizing/reducing reaction | | | | |
| 63-15 | Flammability | | | | |
| 63-16 | Explodability | | | | |
| 63-17 | Storage stability | | | | |
| 63-18 | Viscosity | | | | |
| 63-19 | Miscibility | | | | |

| | | | | | |
|---|---|---|---|---|---|
| 63-20 | Corrosion characteristics | | | | |
| 63-21 | Dielectric breakdown voltage | | | | |
| §158.135 TOXICOLOGY | | | | | |
| 81-1 | Acute oral LD-50, rat | | | | |
| 81-2 | Acute dermal LD-50 | | | | |
| 81-3 | Acute inhalation, LC-50 rat | | | | |
| 81-4 | Primary eye irritation, rabbit | | | | |
| 81-5 | Primary dermal irritation | | | | |
| 81-6 | Dermal sensitization | | | | |

cant obtained the data from another firm (identify); applicant copied data from a publication; applicant obtained a copy of the data from EPA).

(d) The applicant shall submit with his application a statement that EPA, in its evaluation of the properties, efficacy, and safety of the formulated end-use product, may not consider any data as supporting the application, except the following data:

(1) The data the applicant has submitted to EPA under paragraph (b) of this section;

(2) Other data pertaining to the safety of the product's active ingredients, rather than to the safety of the end-use product; and

(3) Existing tolerances, food additive regulations, exemptions, and other clearances issued under the Federal Food, Drug, and Cosmetic Act.

(e) If the applicant knows that any item of data he submitted under this section was generated by (or at the expense of) another person who originally submitted the data to EPA (or its predecessor, USDA) on or after January 1, 1970, to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, or for reregistration (unless the applicant and the original data submitter have reached written agreement on the amount and the terms of payment of any compensation that may be payable under FIFRA section 3(c)(1)(D)(ii) with regard to approval of the application), the applicant shall submit to EPA a statement that he has furnished to each such identified original data submitter:

(1) A notification of the applicant's intent to apply for registration, including the proposed product name;

(2) An offer to pay the person compensation, with regard to the approval of the application, to the extent required by FIFRA sections 3(c)(1)(D) and 3(c)(2)(D);

(3) An identification of the item(s) of data to which the offer applies;

(4) An offer to commence negotiations to ascertain the amount and terms of compensation to be paid; and

(5) The applicant's name, address, and telephone number.

(f) If the applicant's product contains any active ingredient other than those that are present solely because of the incorporation into the product, during formulation, of one or more other registered pesticide products purchased from another producer, then the applicant shall also comply with § 162.9-5 as to such active ingredient, and the application shall contain an acknowledgment that for purposes of FIFRA section 3(c)(1)(D) the application relies on (and any resulting registration should be regarded as if it were based on the Administrator's consideration of) the following data:

(1) All data submitted or specifically cited by the applicant in support of the registration; and

(2) Each other item of data in the Agency's files which:

(i) Concerns the properties or effects of any such active ingredient; and

(ii) Is one of the types of data that EPA would require to be submitted for scientific review by EPA if the applicant sought the initial registration under FIFRA Section 3(c)(5) of a product with composition and intended uses identical to those proposed for the applicant's product, under the data requirements in effect on the date EPA approves the applicant's present application.

(Secs. 3, 6, and 25 of FIFRA, as amended, 7 U.S.C. 136 *et seq.*)

[44 FR 27953, May 11, 1979]

**§ 162.10 Labeling requirements.**

(a) *General*—(1) *Contents of the label.* Every pesticide products shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) *Prominence and legibility.* (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) *Language to be used.* All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) *Placement of Label*—(i) *General.* The label shall appear on or be securely attached to the immediate container of the pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container throug which the label cannot be clearly rea the label must also be securely a tached to such outside wrapper or cor tainer, if it is a part of the package a customarily distributed or sold.

(ii) *Tank cars and other bulk cor tainers*—(A) *Transportation.* While pesticide product is in transit, the ap propriate provisions of 49 CFR Part 170-189, concerning the transportatio of hazardous materials, and specifica ly those provisions concerning the la beling, marking and placarding of haz ardous materials and the vehicles ca rying them, define the basic Federa requirements. In addition, when an registered pesticide product is trans ported in a tank car, tank truck o other mobile or portable bulk contair er, a copy of the accepted label mus be attached to the shipping paper and left with the consignee at the tim of delivery.

(B) *Storage.* When pesticide proc ucts are stored in bulk container whether mobile or stationary, whic remain in the custody of the user, copy of the label of labeling, includin all appropriate directions for use, sha be securely attached to the containe in the immediate vicinity of the dis charge control valve.

(5) *False or misleading statement* Pursuant to section 2(q)(1)(A) of th Act, a pesticide or a device declare subject to the Act pursuant t § 162.15, is misbranded if its labeling i false or misleading in any particula including both pesticidal and non-pes ticidal claims. Examples of statement or representations in the labelin which constitute misbranding include

(i) A false or misleading statemen concerning the composition of th product;

(ii) A false or misleading statemen concerning the effectiveness of th product as a pesticide or device;

(iii) A false or misleading statemen about the value of the product fo purposes other than as a pesticide o device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indi rectly implying that the pesticide o device is recommended or endorsed b

any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) *Final printed labeling.* (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) *Name, brand, or trademark.* (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for * * *," "Distributed by * * *," or "Sold by * * *" to show that the name is not that of the producer.

(d) *Net weight or measure of contents.* (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68° F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) *Product registration number.* The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run par-

allel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) *Producing establishment registration number.* The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) *Ingredient statement*—(1) *General.* The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) *Position of ingredient statement.* (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears and must be clearly distinguishable from and must not be placed in the body of other text.

(3) *Names to be used in ingredient statement.* The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) *Statements of percentages.* The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) *Accuracy of stated percentages.* The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) *Deterioration.* Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) *Inert ingredients.* The Administrator may require the name of any

inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) *Warnings and precautionary statements.* Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) *Required front panel statements.* With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

| Hazard indicators | Toxicity categories | | | |
|---|---|---|---|---|
| | I | II | III | IV |
| Oral $LD_{50}$ | Up to and including 50 mg/kg. | From 50 thru 500 mg/kg. | From 500 thru 5000 mg/kg. | Greater than 5000 mg/kg. |
| Inhalation $LC_{50}$ | Up to and including .2 mg/liter. | From .2 thru 2 mg/liter | From 2. thru 20 mg/liter | Greater than 20 mg/liter. |
| Dermal $LD_{50}$ | Up to and including 200 mg/kg. | From 200 thru 2000 | From 2,000 thru 20,000 | Greater than 20,000. |
| Eye effects | Corrosive; corneal opacity not reversible within 7 days. | Corneal opacity reversible within 7 days; irritation persisting for 7 days. | No corneal opacity; irritation reversible within 7 days. | No irritation. |
| Skin effects | Corrosive | Severe irritation at 72 hours. | Moderate irritation at 72 hours. | Mild or slight irritation at 72 hours. |

(i) *Human hazard signal word*—(A) *Toxicity Category I.* All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) *Toxicity Category II.* All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) *Toxicity Category III.* All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) *Toxicity Category IV.* All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) *Use of signal words.* Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) *Child hazard warning.* Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) *Statement of practical treatment*—(A) *Toxicity Category I.* A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the

placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) *Other toxicity categories.* The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) *Placement and prominence.* All the require front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

| Size of label front panel in square inches | Points | |
|---|---|---|
| | Required signal word, all capitals | "Keep out of reach of Children |
| 5 and under | 6 | 6 |
| Above 5 to 10 | 10 | 6 |
| Above 10 to 15 | 12 | 8 |
| Above 15 to 30 | 14 | 10 |
| Over 30 | 18 | 12 |

(2) *Other required warnings and precautionary statements.* The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) *Hazard to humans and domestic animals.* (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

| Toxicity category | Precautionary statements by toxicity category | |
|---|---|---|
| | Oral, inhalation, or dermal toxicity | Skin and eye local effects |
| I | Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.]. | Corrosive, causes eye and skin damage [or=skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.] |
| II | May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]. | Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.] |
| III | Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]. | Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists. |
| IV | [No precautionary statements required.] | [No precautionary statements required.] |

(ii) *Environmental hazards.* Where a hazard exists to non target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circum-

stances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral $LD_{50}$ of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute $LC_{50}$ of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral $LD_{50}$ of 100 mg/kg or less, or a subacute dietary $LC_{50}$ of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) *Physical or chemical hazards.* Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

| Flash point | Required text |
|---|---|
| **(A) Pressurized Containers** | |
| Flash point at or below 20° F; if there is a flashback at any valve opening. | Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. |
| Flash point above 20° F and not over 80° F or if the flame extension is more than 18 in long at a distance of 6 in from the flame. | Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. |
| All other pressurized containers | Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting. |
| **(B) Nonpressurized Containers** | |
| At or below 20° F | Extremely flammable. Keep away from fire, sparks, and heated surfaces. |
| Above 20° F and not over 80° F | Flammable. Keep away from heat and open flame. |
| Above 80° F and not over 150° F | Do not use or store near heat or open flame. |

(i) *Directions for Use*—(1) *General requirements*—(i) *Adequacy and clarity of directions.* Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use.* Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular:" and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*—(A) Detailed directions for use may be omitted from labeling of pesticides which are intended

for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(*2*) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(*3*) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(*2*) *Contents of Directions for Use* The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum size as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) *Statement of Use Classification.* By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) *General Use Classification.* Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) *Restricted Use Classification.* Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) *Front panel statement of restricted use classification.* (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 36571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

**§ 162.11 Criteria for determinations of unreasonable adverse effects.**

(a) *Criteria for Issuance of Notice of Intent to Deny Registration, Cancel Registration, or to Hold a Hearing—*(1) *Presumption.* (i) A rebuttable presumption shall arise that a notice of intent to deny registration pursuant to section 3(c)(6) of the Act, a notice of intent to cancel registration pursuant to section 6(b)(1) of the Act, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, as appropriate, shall be issued, upon a determination by the Administrator that the pesticide meets or exceeds any of the criteria for risk set forth in paragraph (a)(3) of this section. Upon such determination, the Administrator shall issue notice by certified mail to the applicant or registrant, as the case may be, stating that the applicant or registrant has the opportunity to submit evidence in rebuttal of such presumption in accordance with paragraph (a)(4) of this section. The applicant or registrant shall have forty-five

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL | | COMMENTS |
|---|---|---|---|---|---|
| | | | REQUIRED | PREFERRED | |
| 1 | Product name | All products | Front panel | Center front panel | |
| 2 | Company name and address | All products | None | Bottom front panel or end of label text | If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc. |
| 3 | Net contents | All products | None | Bottom front panel or end of label text | May be in metric units in addition to U.S. units |
| 4 | EPA Est. No. | All products | None | Front panel | Must be in similar type size and run parallel to other type. |
| 5 | EPA Reg. No. | All products | None | Front panel, immediately before or following Reg. No. | May appear on the container instead of the label. |
| 6A | Ingredients statement | All products | Front panel | Immediately following product name | Text must run parallel with other text on the panel. |
| 6B | Pounds/gallon statement | Liquid products where dosage given as lbs. ai/unit area | Front panel | Directly below the main ingredients statement | |
| 7 | Front panel precautionary statements | All products | Front panel | | All front panel precautionary statements must be grouped together, preferably blocked. |
| 7A | Keep Out of Reach of Children (Child hazard warning) | All products | Front panel | Above signal word | Note type size requirements. |
| 7B | Signal word | All products | Front panel | Immediately below child hazard warning | Note type size requirements. |

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL | | COMMENTS |
|---|---|---|---|---|---|
| | | | REQUIRED | PREFERRED | |
| 7C | Skull & cross-bones and word POISON (in red) | All products which are Category I based on oral, dermal, or inhalation toxicity | Front panel | Both in close proximity to signal word | |
| 7D | Statement of practical treatment | All products in Categories I, II, and III | Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements. | Front panel for all. | |
| 7E | Referral statement | All products where precautionary labeling appears on other than front panel. | Front panel | | |
| 8 | Side/back panel precautionary statements | All products | None | Top or side of back panel preceding directions for use | Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked. |
| 8A | Hazards to humans and domestic animals | All products in Categories I, II, and III | None | Same as above | Must be preceded by appropriate signal word. |
| 8B | Environmental hazards | All products | None | Same as above | Environmental hazards include bee caution where applicable. |

| ITEM | LABEL ELEMENT | APPLICABILITY OF REQUIREMENT | PLACEMENT ON LABEL | | COMMENTS |
|---|---|---|---|---|---|
| | | | REQUIRED | PREFERRED | |
| 8C | Physical or chemical hazards | All pressurized products, others with flash points under 150°F | None | Same as above | |
| 9A | Restricted block | All restricted products | Top center of front panel | Preferably blocked | Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word. |
| 9C | Misuse statement | All products | Immediately following statement of classification or ahead of directions for use | | |
| 10A | Re-entry statement | All cholinesterase inhibitors | In the directions for use | Immediately after misuse statement | |
| 10C | Storage and disposal block | All products | In the directions for use | Immediately before specific directions for use or at the end of directions for use | Must be set apart and clearly distinguishable from from other directions for use. |
| 10D U.S. | Directions for use | All products | None | None | May be in metric as well as U.S. units |

## PHYSICAL-CHEMICAL HAZARDS

| Criteria | Required Label Statement |
|---|---|
| I. Pressurized Containers | |
| A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening. | Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening. | Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| C. ALL OTHER PRESSURIZED CONTAINERS | Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting. |
| II. Non-Pressurized Containers | |
| A. Flashpoint at or below 20°F. | Extremely flammable. Keep away from fire, sparks, and heated surfaces. |
| B. Flashpoint above 20°F and over 80°F. | Flammable. Keep away from heat and open flame. |
| C. Flashpoint over 80°F and not over 150°F. | Do not use or store near heat and open flame. |
| D. Flashpoint above 150°F. | None required. |

## STORAGE AND DISPOSAL INSTRUCTIONS FOR PESTICIDES

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL." The STORAGE AND DISPOSAL heading must appear in the minimum type size listed below:

| Size of label front panel in square inches | Required type size for the heading STORAGE AND DISPOSAL (all capitals) |
|---|---|
| 10 and under | .6 point |
| Above 10 to 15 | .8 point |
| Above 15 to 30 | 10 point |
| Over 30 | 12 point |

Storage and disposal instructions must be set apart and clearly distinguishable from other directions for use. Blocking storage and disposal statements with a solid line is suggested as a means of increasing their prominence.

A. Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

B. Pesticide Disposal Instructions:

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients appearing on the "Acutely Hazardous" Commercial Pesticide Products List (RCRA "E" List) at the end of this appendix or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, skin or eye irritation potential, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

   "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

   The labels of all products, except those intended for domestic use, containing active or inert ingredients that appear on the "Toxic" Commercial Pesticide Products List (RCRA "F" List) at the end of this appendix or presently meet any of the criteria in Subpart C, 40 CFR 261 for a hazardous waste must bear the following pesticide disposal statement:

"Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

"Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

3. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

C. Container Disposal Instructions

The label of each product must bear container disposal instructions appropriate to the type of container.

1. All products intended for domestic use must bear one of the following container disposal statements:

| Container Type | Statement |
|---|---|
| Non-aerosol products (bottles, cans, jars) | Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash. |
| Non-aerosol products (bags) | Do not reuse bag. Discard bag in trash. |
| Aerosol products | Replace cap and discard containers in trash. Do not incinerate or puncture. |

2. The labels for all other products must bear container disposal instructions, based on container type, listed below:

| Container Type | Statement |
|---|---|
| Metal containers (non-aerosol) | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities. |
| Plastic containers | Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke. |
| Glass containers | Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures. |

| Container Type | Statement |
|---|---|
| Fiber drums with liners | Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner. |
| Paper and plastic bags | Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke. |
| Compressed gas cylinders | Return empty cylinder for reuse (or similar wording). |

[1]Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

2. The labels for all other products must bear container disposal instructions, based on container type, listed on the first page of this Appendix.

Pesticides that are hazardous wastes under 40 CFR 261.33(e) and (f) when discarded.

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients, (no inerts):

Acrolein
Aldicarb
Aldrin
Allyl alcohol
Aluminum phosphide
4-Aminopyridine
Arsenic acid
Arsenic pentoxide
Arsenic trioxide
Calcium cyanide
Carbon disulfide
p-Chloroaniline
Cyanides (soluble cyanide salts, not specified elsewere)
Cyanogen chloride
2-Cyclohexyl-4,6-dinitrophenol
Dieldrin
0,0-Diethyl S-[2-ethylthio)ethyl] phosphorodithioate
(disulfoton, Di-Syston)
0,0-Diethyl 0-pyrazinyl phosphorothioate (Zinophos)
Dimethoate
0,0-Dimethyl 0-p-nitrophenyl phosphorothioate (methyl parathion)
4,6-Dinitro-o-cresol and salts
4,6-Dinitro-o-cyclohexylphenol
2,4 Dinitrophenol
Dinoseb
Endosulfan
Endothall
Endrin
Famphur
Fluoroacetamide
Heptachlor
Hexanethyl tetraphosphate
Hydrocyanic acid
Hydrogen cyanide
Methomyl
alpha-Napthylthiourea (ANTU)
Nicotine and salts
Octamethylpyrophosphoramide (OMPA, schradan)
Parathion

"Acutely Hazardous" Commercial Pesticides (RCRA "E" List)
Active Ingredients continued:

Phenylmercuric acetate (PMA)
Phorate
Potassium cyanide
Propargyl alconol
Sodium azide
Sodium cyanide
Sodium fluoroacetate
Strychnine and salts
0,0,0,0-Tetraethyl dithiopyrophosphate (sulfotepp)
Tetraethyl pyrophosphate
Thallium sulfate
Thiofanox
Toxaphene
Warfarin
Zinc phosphide

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There are currently no inert ingredients for commercial pesticides on the "Acutely Hazardous" List (RCRA "E" List).

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Acetone
Acrylonitrile
Amitrole
Benzene
Bis(2-ethylhexyl)pthalate
Cacodylic acid
Carbon tetrachloride
Chloral (hydrate)
Chlordane (technical)
Chlorobenzene
4-Chloro-m-cresol
Chloroform
o-Chlorophenol
4-Chloro-o-toluidine hydrochloride
Creosote
Cresylic acid
Cyclohexane
Decachlorooctahydro-1,3,4-metheno-2H-cyclobuta[c,d]-pentalen-2-one (kepone, chlordecone)
1,2-Dibromo-3-chloropropane (DBCP)
Dibutyl phthalate
S-3,3-(Dichloroallyl diisopropylthiocarbamate (diallate, Avadex)
o-Dichlorobenzene
p-Dichlorobenzene
Dichlorodifluoromethane (Freon 12®)
3,5-Dichloro-N-(1,1-dimethyl-2-propynyl) benzamide (pronamide,Kerb)
Dichloro diphenyl dichloroethane (DDD)
Dichloro diphenyl trichloroethane (DDT)
Dichlorethyl ether
2,4-Dichlorophenoxyacetic, esters and salts (2,4-D)
1,2-Dichloropropane
1,3-Dichloropropane (Telone)
Dimethyl phthalate
Ethyl acetate
Ethyl 4,4'-dichlorobenzilate (chlorobenzilate)
Ethylene dibromide (EDB)
Ethylene dichloride
Ethylene oxide
Formaldehyde
Furfural
Hexachlorobenzene
Hexachlorocyclopentadiene
Hexachloroethane
Hydrofluoric acid

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Active Ingredients:

Isobutyl alcohol
Lead acetate
Lindane
Maleic hydrazide
Mercury
Methyl alcohol
Methyl bromide
Methyl chloride
2,2'-Methylenebis (3,4,6-trichlorophenol) (hexachlorophene)
Methylene chloride
Methyl ethyl ketone
4-Methyl-2-pentanone (methyl isobutyl ketone)
Naphthalene
Nitrobenzene
p-Nitrophenol
Pentachloroethane
Pentachloronitrobenzene (PCNB)
Pentaclorophenol
Phenol
Phosphorodithioic acid, 0,0-diethyl, methyl ester
Propylene dichloride
Pyridine
Resorcinol
Safrole
Selenium disulfide
Silvex
1,2,4,5-Tetrachlorobenzene
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
2,3,4,6-Tetrachlorophenol
Thiram
Toluene
1,1,1-Trichloroethane
Trichloroethylene
Trichloromonofluoromethane (Freon 11®)
2,4,5-Trichlorophenol
2,4,6-Trichlorophenol
2,4,5-Trichlorophenoxyacetic acid (2,4,5-T)
Xylene

"Toxic" Commercial Pesticide Products (RCRA "F" List)
Inert Ingredients:

Acetone
Acetonitrile
Acetophenone
Acrylic acid
Aniline
Benzene
Chlorobenzene
Chloroform
Cyclohexane
Cyclohexanone
Dichlorodifluoromethane (Freon 12®)
Diethyl phthalate
Dimethylamine
Dimethyl phthalate
1,4-Dioxane
Ethylene oxide
Formaldehyde
Formic acid
Isobutyl alcohol
Meleic annydride
Methyl alconol (methanol)
Methyl ethyl ketone
Methyl methacrylate
Naphthalene
Saccharin and salts
Thiourea
Toluene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichlorofluoromethane (Freon 11®)
Vinyl chloride
Xylene

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

CERTIFIED MAIL

SUBJECT: Initiation of Reregistration Process for Pesticide Products Containing Butylate as the Single Active Ingredient

Dear Registrant:

In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA's Office of Pesticide Programs has begun the reregistration process for pesticide products containing the subject ingredient. Significant changes to the statute were made in 1972, 1975, and 1978; thus, current requirements may be substantially different from those in effect at the time your product(s) were registered. The first phase of reregistration requires that you (1) make a commitment to the Agency regarding data development and (2) subsequently submit revised product labeling and associated information.

This mailing contains the Guidance Document for preparation of submissions, as well as a listing of your affected product(s) (Attachment A), and a separate list of registrants with products subject to this standard and which contain this active ingredient (Attachment B). The latter list is for the purpose of cooperative data development.

The Guidance Document sets out the Agency's evaluation of all available data pertaining to the subject chemical and its registered uses, and its rationale for the regulatory actions being taken at this time. Additionally, the Guidance Document contains instructions describing certain of the steps you must take to maintain registration for your product(s).

Products not brought into compliance with the Guidance Document as supplemented by subsequent information from EPA about compliance with certain data support requirements will be subject to suspension and/or cancellation.

Specifically, the enclosed Guidance Document does the following:

1. Introduces the purpose of this document.

2. Explains the Agency's policy regarding data submission and identifies, in table format, the data that must be submitted to complete the Agency's evaluation of each product. In addition, a bibliography identifying the data which is considered part of the data base supporting the registration standard is included.

3. Sets out time-frames for submission of required data.

4. Explains how to revise labeling for maufacturing use products. (As the Guidance Document explains, labeling is not required at this time.)

5. Provides submission instructions.

Because of the variety and complexity of the requirements, and the short statutory time-frames available for certain actions, it is essential that you understand the specific requirements and procedures in order that you may respond in a correct and timely manner. Since a part of these requirements is under Section 3(c)(2)(B) of FIFRA, your first response may be required within 90 days from receipt of this letter. Please note that <u>if you do not respond or do not comply fully with the requirements, your application may be rejected or your product registration cancelled or suspended</u>.

If, after reviewing this material, you do not understand what you must do or how or when you must respond, please contact the Product Manager listed below who will assist you in every reasonable way. If you wish to discuss the data requirements or request that certain data be waived, you must write to the Agency and indicate those data requirements with which you take issue and your rationale for doing so. After the Agency has had a chance to review your submission, the Product Manager will contact you to set up a meeting for the purpose of resolving all issues relative to data requirements.

Please note that this guidance document will eventually be supplemented by EPA with additional information about compliance with data support requirements. In Monsanto v. Administrator, EPA was recently enjoined by the District Court for the Eastern District of Missouri from implementing in any way the "mandatory data licensing" aspects of §3(c)(1)(D) of FIFRA. EPA is assessing the implications of the injunction for the reregistration process. Because of this unresolved situation, EPA has decided to proceed with the requirements in this guidance package which do not relate to the "data licensing" issue and to supplement the package with additional guidance when circumstances permit.

If you have any questions concerning this Guidance Document, you may contact the Product Manager listed below:

Robert J. Taylor, Product Manager 25
Environmental Protection Agency
Registration Division (TS-767)
Office of Pesticide Programs
Washington, D.C. 20460
Telephone 703/557-1800

Sincerely,

Douglas D. Campt, Director
Registration Division (TS-767)

Enclosure